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<u>Ajaz Hussain, Ph.D.</u>	<u>October 1997</u>
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## TABLE OF CONTENTS

## DESCRIPTIVE AND SAFETY

Introduction, Text of Report .....	1- 12
Subject Description .....	13
Randomization Code .....	14
Study Dates .....	15
Table 4 (Pharmacokinetic Specimen Times) .....	16-25
Table 5 (Subject Screening Parameters) .....	26
Table 6, Figures 1-10 (Subject Vital Signs) .....	27-53
Table 7, (Female Subject Pregnancy Test) .....	54
Table 8, Figures 11-22 (Hematological Parameters) .....	55-80
Table 9, Figures 23-27 (Electrolytes) .....	81-90
Table 10, Figures 28-45 (Laboratory Profile, Chem 20) .....	91-126
Table 11, Figures 46-48 (Urinalysis) .....	127-134

## PHARMACOKINETIC AND PHARMACODYNAMIC

Figure 49 (a-p) Halofantrine Accumulation Kinetics .....	135-150
Figure 50 Halofantrine Steady State Oral Clearance .....	151
Table 12, Figures 51-54 (ECG Parameters) .....	152-178
Table 13, Halofantrine Conc, ECG (Raw Data) .....	179-209
Figure 55 (a-q) Halofantrine Conc/Time Graphs .....	210-223
Figures 56-70 Halofantrine Conc vs QTc .....	224-254



## INTRODUCTION:

Halofantrine HCl is an antimalarial drug approved by the FDA for the treatment of mild to moderate malaria caused by *Plasmodium falciparum* or *Plasmodium vivax*(1). The present study was designed to investigate the safety, tolerance and pharmacokinetics of halofantrine HCl given in multiple doses in a Phase I study as part of the overall development of halofantrine as a *prophylactic* antimalarial drug.

## RATIONALE FOR STUDY:

Mefloquine HCl and doxycycline hyclate are the only Department of Defense (DOD) pharmaceutical preparations currently approved for prophylaxis against chloroquine-resistant *Plasmodium falciparum* (2). Each of these prophylactic agents has its own spectrum of side-effects that may limit its use in individual patients. In addition, changing resistance patterns worldwide necessitates the development of additional chemoprophylactic agents against this potentially deadly disease. Halofantrine may show promise as an alternative prophylactic therapy, however a number of clinical reports have suggested possible cardiotoxicity of halofantrine in the form of electrocardiographic QT prolongation and associated torsade de pointe arrhythmia(3-6). Therefore careful reevaluation of halofantrine safety when it is being considered for use as prophylaxis in healthy people is necessary.

This Phase I safety and tolerance study was designed to evaluate halofantrine given daily at the maximal dose for which absorption is linear and for which there is limited safety data. The period of dosing for this Phase I safety and tolerance study corresponded to the length of time that dosing would be required for a subsequent Phase IIa experimental sporozoite challenge study, dose-optimization study.

## STUDY OBJECTIVES:

The prospectively defined objectives of this Phase I study were as follows:

1. To evaluate the safety and tolerance of halofantrine hydrochloride given over time to healthy adults.
2. To characterize the variability of multi-dose halofantrine pharmacokinetics over time in healthy adults.
3. To correlate pharmacodynamics (electrocardiographic QT intervals) with pharmacokinetics (plasma concentrations of halofantrine/desbutylhalofantrine).

## STUDY DESIGN:

The study design was a randomized, double-blind, placebo-controlled Phase I safety and tolerance study. Twenty-one healthy volunteers were randomly assigned to receive

halofantrine or placebo. Initially it was planned to study 16 subjects, with 12 subjects to receive active drug (halofantrine) and 4 subjects to receive placebo, however due to subject drop outs prior to study completion, the number to be enrolled was increased to increase the number of subjects who completed the entire study. The blind was maintained with the increase in sample size accomplished by stratified randomization. Subjects were dosed daily for 42 days with 500 mg halofantrine hydrochloride. Subjects were fasted for at least 2 hours prior to and 2 hours following the oral dose. The initial 21 days of drug administration were done with subjects confined as inpatients to the Georgetown University Medical Center Clinical Research Center and during the remaining 21 days of drug administration the subject reported daily to the Clinical Research Center for medical assessment and supervised drug administration. The subjects were then followed periodically for the next 4 1/2 months with medical assessments and pharmacokinetic sampling at the Clinical Research Center.

#### **CONDUCT OF THE STUDY:**

The study was conducted at the Georgetown University Clinical Research Center at Georgetown Medical Center, 3800 Reservoir Road NW, Washington, DC. Each subject was an inpatient for 3 weeks during the period between December 21, 1995 and December 27, 1996. The last subject completed the study June 3, 1997. The Principal Investigator was Darrell R. Abernethy, M.D., Ph.D., who is Director of the Georgetown Medical Center Clinical Research Center, Professor of Medicine and Pharmacology, and Director of the Division of Clinical Pharmacology at Georgetown University. Collaborative Investigators included David L. Wesche, M.D., Ph.D. and Brian G. Schuster, M.D., of the Division of Experimental Therapeutics, Walter Reed Army Institute of Research, David Flockhart, M.D., Ph.D., and Jean Barbey, M.D., of the Division of Clinical Pharmacology at Georgetown University Medical Center.

The protocol and informed consent for this study were reviewed and approved by the Georgetown University Institutional Review Board August 1, 1995. Initial recruitment was by word of mouth, however to complete enrollment newspaper advertisement was used. Proposed advertisement for the study was reviewed and approved March 12, 1996. There was also approval of the protocol and informed consent form by the U.S. Army Surgeon General's Human Subjects Research Review Board. Twenty-one healthy male and female subjects were recruited by word of mouth and advertisement in the Washington Post newspaper. All subjects met the protocol inclusion criteria and did not meet the protocol defined exclusion criteria. These were:

#### **Inclusion criteria:**

1. Aged 18-45 years inclusive
2. Male or non-pregnant, non-lactating females
3. Weight within 20% of ideal body weight as defined by Metropolitan Life Tables
4. Normal history and physical examination
5. Normal serum chemistries including Mg++

6. Normal CBC
7. Negative HIV screen
8. Negative hepatitis screen
9. Negative serum beta-HCG pregnancy test (females only)
10. Normal electrocardiogram
11. Normal chest X-ray
12. Normal pulmonary function tests with normal DLCO2
13. Negative urine drug screen
14. Normal urinalysis
15. Normal TSH
16. Available for the full duration of the study and willing to comply with study procedures
17. Provision of written informed consent

**Exclusion criteria: Any subject with:**

1. History of serious medical problems, including any kind of heart disease
2. Allergy to halofantrine or related drugs
3. Taken any medication one week prior to study
4. Donated blood or participated in another investigational drug study within the past 2 months
5. History of alcohol or drug abuse
6. Cigarette smoking or use of any tobacco product
7. Pregnancy, unwillingness to use adequate contraception, or the desire to become pregnant within 6 months of the last dose of study drug
8. Prior upper gastrointestinal surgery
9. HIV positivity or other clinically significant laboratory abnormalities including hyperlipidemia
10. Inability to speak or understand English
11. Unusual dietary habits

Each of the subject volunteers also had a screening physical examination and laboratory study as outlined in the protocol. Any candidate with significant clinical or laboratory abnormality was excluded from participation and referred for appropriate health care follow-up.

Demographics of the 21 subject participants are outlined in Table 1. In summary, they ranged in age for 21-44 years, there were 18 males and 3 females, 8 Caucasian and 13 Black, their weight range was 63-96 kg, and their height range was 62-73 inches.

Subjects were randomized to receive either active or placebo halofantrine in a 4:1 ratio with the randomization blinded and maintained by Dr. Mark Sale, a member of the Division of Clinical Pharmacology at Georgetown Medical Center. The randomization allocation of subject participants is outlined in Table 2. The test material was halofantrine hydrochloride 250 mg tablets. The material was provided by the US Army, however the

original source was noted to be SmithKline Beecham Pharmaceuticals, Welwyn Garden City, Herts, U.K. The tablets were noted to be lot #G1905/V001.

All drug doses were administered in the morning following at least 2 hours fast, with fasting continued for 2 hours following the drug administration. The first 21 daily doses were administered while the subjects were confined the inpatient unit. On day 22 the subjects were discharged from the inpatient unit and they returned daily for their morning observed dose from day 22 to day 41. At that time they were readmitted to the inpatient unit to receive the last dose of halofantrine and have clinical evaluation, safety laboratory determinations, and blood sampling for pharmacokinetic evaluation. On day 43 the subjects were discharged from the inpatient unit to return to the outpatient area on study days 44, 45, 48, 51, 54, 57, 72, and 180.

Subjects 001, 003, 006, 007, 009, 012, 013, 015, 019, 020, and 021 completed the entire 180 days of the study. Subject 017 received only 2 doses of drug, therefore safety information was collected, however this subject was not included as one of the 20 with sufficient data for some evaluation. The other subjects, 002, 004, 005, 008, 010, 011, 014, 016, and 018 completed various proportions of the study before dropping out (Table 3). No subjects were discontinued for adverse events, however 3 adverse events, gastroenteritis (subject 002), skin rash (subject 006), and headaches (subject 011) were noted. The gastroenteritis was associated in time with a food ingestion (about 6 hours later) that seemed the most likely cause, although drug exposure could not be ruled out. The skin rash disappeared while the subject remained on drug and the subject completed the study, therefore it was deemed unlikely to be related to drug exposure. The headaches were temporally related to drug exposure for several days and were deemed to be likely related to drug exposure. An outline of study participation by the subjects is noted in Table 3.

Blood sampling for pharmacokinetic analysis and electrocardiograms for QTc analysis were obtained as follows:

<u>Day</u>	<u>Time after dose (hr)</u>
1	predose (1/2 hr)
1	0.5
1	1
1	2
1	3
1	4
1	6
1	8
1	10
1	12
2	predose
3	predose
4	predose
4	2
4	4
4	6
4	8
4	12
5	predose
6	predose
7	predose
7	2
7	4
7	6
7	8
7	12
8	predose
9	predose
10	predose
11	predose
12	predose
13	predose
14	predose
14	2
14	4
14	6
14	8
14	12

<u>Day</u>	<u>Time after dose (hr)</u>
15	predose
16	predose
17	predose
18	predose
19	predose
20	predose
21	predose
21	2
21	4
21	6
21	8
21	12
25	predose
29	predose
32	predose
36	predose
39	predose
42	predose
42	0.5
42	1
42	2
42	3
42	4
42	6
42	8
42	10
42	12
43	am
44	am
45	am
48	am
51	am
54	am
57	am
72	am
180	am

Each sampling time point, scheduled and actual, is listed in Table 4. As can be seen, the inpatient samples were obtained within a few minutes of the scheduled time, with outpatient samples for the most part within 1-2 hours of the scheduled time. For pharmacokinetic samples that deviate significantly from the scheduled time, the analysis uses the actual time of collection for purposes of calculation. All blood samples were

centrifuged in a refrigerated centrifuge promptly, the plasma separated, and stored at -70 C until time of shipment. All samples were shipped on dry ice.

Analysis of electrocardiographic data was as follows. All ECGs were 12 lead with a 15 second 3-lead rhythm strip (I, aVF, V2). The chart speed for recording the 12 lead ECG was 25 mm/sec, the speed for the rhythm strip was 50 mm/sec. Two copies of each ECG were recorded, one for the chart and one for interpretation. For each ECG the RR interval and QT interval were measured for the first 3 consecutive normal and technically acceptable complexes and the results were averaged. If the RR interval was greater than 500 msec, QTc was calculated according to the Bazett formula(7). If the RR interval was less than 500 msec, the Fridericia correction was used(8). QT interval measurement was based on a modification of the method of Lepeschkin et al(9). The ECG tracings were placed on a digitizing pad and a cross-hair type pointing device was used to mark the beginning and the end of each interval. The data were transmitted to and stored on computer. The QT duration was measured on the rhythm strips from three leads simultaneously with use of the earliest beginning of the QRS complex to the end of the longest T wave in any of the three simultaneous leads. The end of each T wave was determined by drawing a tangent to the steepest portion of the downsloping T wave. The point at which this tangent intersected with the isoelectric line was used to designate the end of the T wave.

In addition to the above mentioned procedures, questioning regarding adverse reactions and subjective symptomatology, vital sign determinations and determination of laboratory safety parameters were performed as outlined in the study protocol. Deviations have been noted in the specific case report forms. These data are recorded for each subject in the subject's case report form. Copies of case report forms have been appropriately completed for each subject and have been periodically reviewed by the USAMMDA monitor. These forms are on file and available at the Georgetown University Clinical Research Center.

Periodically, according to the protocol-defined procedure, plasma samples were shipped on dry ice to Dr. Emil Lin at the Drug Studies Unit, School of Pharmacy, University of California at San Francisco. Quality control and reporting of plasma concentration data was monitored separately from clinical site monitoring.

## RESULTS:

The study findings will be separated into 5 sections as follows: (1) Clinical Adverse Experiences, (2) Laboratory Safety Parameters, (3) Pharmacokinetic Results, (4) Pharmacodynamic [Electrocardiographic] Results, and (5) Pharmacokinetic / Pharmacodynamic Concentration Effect Relationships.

**1. Clinical Adverse Experiences.** Subject 002 (21 year old Black male) experienced stomach cramping, diarrhea, and fever for 4 days starting day 31 of the study. This began a few hours after ingestion of some possibly contaminated food. The subject stated he had

eaten salmon with a friend and the friend had become ill with similar symptoms. Evaluation on day 32 revealed mild abdominal tenderness and no other significant findings. At that time CBC showed 8000 WBC, Hb 14.2 and Hct 42.3. Symptoms subsided spontaneously on day 35. This subject was receiving halofantrine. He discontinued study on day 36 for personal reasons. Subject 006 (26 year old White male) developed a localized skin rash on day 11. Local care was administered and by day 15, while the subject remained on study the rash resolved. This subject was receiving placebo. Subject 011 (43 year old Black Hispanic female) complained of a throbbing headache on day 7. This was considerably relieved by a 650 mg dose of acetaminophen. The headache recurred on days 10, 12, 19, 21, and 22. Physical examination was unrevealing at the various evaluations during this series of headaches. This subject was receiving halofantrine. The subject did not subsequently complain of headache. Based on the history and examination, I deemed the subject 002 and subject 006 events to be unlikely to be related to halofantrine, and the subject 011 event to be probably related to halofantrine.

**2. Laboratory Safety Parameters.** Screening laboratory parameters for inclusion into the study are shown in Table 5 and include Drug Screen, Chest X-ray, Pulmonary function tests (screen and day 42), TSH, HIV, Hepatitis Surface Antigen (HBsAg), Hepatitis C (HbC), and Hepatitis C antibody (HbC antibody).

Vital signs during the course of the study are shown in Table 6(a-e) and include systolic blood pressure, diastolic blood pressure, heart rate, temperature, and weight. Each of these parameters is followed by 2 figures that plot the values and variance. This first figure shows the data in a linear array and includes maximum and minimum values, while the second figure shows the data with standard deviation plotted on a true time scale (Figures 1-10). Of interest, systolic and diastolic blood pressure and heart rate tended to be less during the inpatient part of the protocol (days 1-22). Early in the study weight was not measured daily, therefore missing data appear as empty cells in this table.

Beta HCG for female subjects (003, 010, 011) is shown in Table 7 and data are included for the duration of their participation (only 003 completed the study).

Hematological profile during the course of the study is shown in Table 8(a-l) and includes WBC, hemoglobin, hematocrit, RBC, red cell indices (MCV, MCHC, MCH), reticulocyte count, and white cell differential (eosinophils, segmented neutrophils, monocytes, lymphocytes). Values outside of the laboratory normal range are bolded. Each table is followed by a figure which plots the mean, standard deviation, and extreme values for the respective parameter (Figures 11-22). No trend for change in hematological parameters could be discerned during and following drug exposure. Missing data and data not obtained due to subject dropout are shown as empty cells.

Electrolytes during the course of the study are shown in Table 9(a-e) and include sodium, chloride, potassium, carbon dioxide, and glucose. Values outside of the laboratory normal range are bolded. Each table is followed by a figure which plots the mean, standard



deviation, and extreme values for the respective parameter (Figures 23-27). No trend for change in electrolytes, CO<sub>2</sub>, or glucose could be discerned during the course of the study. Missing data and data not obtained due to subject dropout are shown as empty cells.

Other chemistries during the course of the study are shown in Table 10(a-s) and include alkaline phosphatase, albumin, total bilirubin, blood urea nitrogen, calcium, total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, creatinine, gGT, LDH, magnesium, phosphate, total protein, AST, ALT, and uric acid. Each table is followed by a figure which plots the mean, standard deviation, and extreme values for the respective parameter (Figures 28-45). No trend for change in other chemistries could be discerned during the course of the study. Missing data and data not obtained due to subject dropout are shown as empty cells.

Urinalysis with microscopic examination is shown in Table 11(a-e) and includes casts, occult blood, RBC, WBC, and specific gravity. Each table is followed by a figure which plots the mean, standard deviation, and extreme values for the respective parameter (Figures 46-48). Occult blood noted for subjects 003 and 010 was observed during menses for these female subjects. No trend for change in urinalysis parameters was noted throughout the course of the study.

**3. Pharmacokinetics:** The pharmacokinetic parameters which could be evaluated with a degree of reliability were accumulation rate constant and accumulation half-life for each of the halofantrine stereoisomers (+Halofantrine and -Halofantrine) and steady state oral clearance for each of the isomers. Accumulation rate constants were determined from all trough (prior to the next dose) concentrations for days 1-45, the time of daily oral dosing of 500 mg/day racemic Halofantrine hydrochloride. Steady state oral clearance was determined from the mean of the measured trough concentrations from dosing days 23-45, which on visual inspection provided a reasonable description of steady state. Fitted functions for each subject, calculated accumulation rate constants and half lives are shown on Figure 49 (a-p). Calculated values were: +Halofantrine;  $0.161 \pm 0.120$  days<sup>-1</sup> and  $7.01 \pm 4.80$  days respectively and -Halofantrine;  $0.184 \pm 0.191$  days<sup>-1</sup> and  $7.25 \pm 4.82$  days respectively. Similarly steady state concentrations and oral clearance are shown on Figure 50. Observed and calculated values were: +Halofantrine;  $88.8 \pm 46.2$  ng/ml and  $139 \pm 73.0$  L/hr respectively and -Halofantrine;  $43.7 \pm 17.3$  ng/ml and  $265.2 \pm 135.4$  L/hr respectively. It is worth noting that +Halofantrine has markedly higher steady state concentrations across the group and this is reflected in the oral clearance calculation, which is about 1/2 that seen for -Halofantrine.

**4. Pharmacodynamics (Electrocardiographic Effects):** Electrocardiographic parameters during the course of the study are shown in Table 12 (a-d) including heart rate, PR interval, QRS duration, and QTc calculated as described above. Following each table is a plot of mean, standard deviation, and extreme values for each ECG (Figures 51-54). No trend for change in heart rate, PR interval, or QRS duration could be discerned. In contrast, QTc interval tended to be prolonged from baseline in subjects 002, 007, 009,

010, 011, 014, 016, 018, and 021. These subjects were all receiving halofantrine, and none of the subjects receiving placebo had an appreciable change in QTc.

**5. Concentration Effect (Pharmacokinetic/Pharmacodynamic) Relationships:** Raw data depicting measured ECG QTc and concentrations of the stereoisomers of halofantrine and its major metabolite, desbutylhalofantrine are shown in Table 13 (a-o). Subjects who received placebo of course are not represented as they have no halofantrine concentration determinations. Concentration time plots for isomers of halofantrine and desbutylhalofantrine are shown in Figure 55 (a-o). Linear regressions of +halofantrine and ECG QTc and -halofantrine and ECG QTc are depicted in figures 56-70. It is clear that in most subjects a strong relationship between halofantrine concentration and lengthening QTc exists (Subjects 1,2,4,8,9,10,11,14,15,16,18, and 20) and that there is little relationship for others (Subjects 5,7,19).

## CONCLUSIONS:

This halofantrine regimen of 500 mg per os once daily administered in the fasting state for a period of 6 weeks was well tolerated by the subject participants. Clinical adverse effects were few and minor. Laboratory safety profiles showed no evidence of abnormality associated with drug exposure. Electrocardiographic QTc prolongation in the range of 5-15% occurred in most subjects who received halofantrine, and did not occur in subjects who received placebo. In most instances a linear relationship between increasing concentrations of each of the halofantrine stereoisomers and lengthening of the ECG QTc could be demonstrated. Since racemic halofantrine was administered concentrations of each of the isomers covaried, therefore no conclusion can be reached from this study about the relative contribution to QTc prolongation from the respective isomers.

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Darrell R. Abernethy, M.D., Ph.D.  
Principal Investigator

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Date

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Table 1

HALOFANTRINE SUBJECT DEMOGRAPHICS									
Subject Number	Initials	Race	Gender	Age	Weight (kg)	Height (in)	Hosp Day 0	Date Dropped	Study Completed
1	JKS	W	M	23	64	67	12/21/95		06/18/96
2	BSH	B	M	21	96	68	12/21/95	01/25/96	
3*	EJW	W	F	23	68	70	12/21/95		06/18/96
4	WPS	B	M	27	68	71	01/10/96	02/16/96	
5	SGA	B	M	35	68	70	01/10/96	02/07/96	
6*	JBC	W	M	26	77		01/25/96		07/23/96
7	DAN	W	M	33	73	68	02/15/96		08/13/96
8	AYB	B	M	28	64	67	02/15/96	02/25/96	
9	GRL	W	M	38	75	71	02/15/96		08/13/96
10	EYJ	B	F	39	75	65	02/15/96	04/09/96	
11	C-E	B (Hispanic)	F	43	66	52	02/23/96	04/08/96	
12*	HLL	B	M	37	82	71	03/14/96		09/10/96
13*	GLG	W	M	35	63	67	03/28/96		10/08/96
14	DLS	B	M	43	75	68	03/28/96	05/07/96	
15	DMK	B	M	28	71	63	03/28/96		09/24/96
16	L-W	B	M	44	77	73	03/28/96	05/11/96	
17	LDG	B	M	21	68	70	08/01/96	08/02/96	
18	KLS	B	M	36	68	69	08/01/96	10/02/96	
19	WSB	W	M	43	82	71	08/22/96		02/18/97
20	K-P	B	M	22	75	70	10/31/96		04/28/97
21*	CAE	W	M	38	92	69	12/05/96		06/03/97
* denotes Placebo									

Table 2

RANDOMIZATION CODE	
Subject No.	Assignment
1	Halofantrine
2	Halofantrine
3	Placebo
4	Halofantrine
5	Halofantrine
6	Placebo
7	Halofantrine
8	Halofantrine
9	Halofantrine
10	Halofantrine
11	Halofantrine
12	Placebo
13	Placebo
14	Halofantrine
15	Halofantrine
16	Halofantrine
17	Halofantrine
18	Halofantrine
19	Halofantrine
20	Halofantrine
21	Placebo

Table 3

HALOFANTRINE STUDY PARTICIPATION DATES					
Subject Number	Initials	Hospital Day 0	Date Dropped	Study Completed	
1	JKS	12/21/95		06/18/96	
2	BSH	12/21/95	01/25/96		
3	EJW	12/21/95		06/18/96	
4	WPS	01/10/96	02/16/96		
5	SGA	01/10/96	02/07/96		
6	JBC	01/25/96		07/23/96	
7	DAN	02/15/96		08/13/96	
8	AYB	02/15/96	02/25/96		
9	GRL	02/15/96		08/13/96	
10	EYJ	02/15/96	04/09/96		
11	C-E	02/23/96	04/08/96		
12	HLL	03/14/96		09/10/96	
13	GLG	03/28/96		10/08/96	
14	DLS	03/28/96	05/07/96		
15	DMK	03/28/96		09/24/96	
16	L-W	03/28/96	05/11/96		
17	LDG	08/01/96	08/02/96		
18	KLS	08/01/96	10/02/96		
19	WSB	08/22/96		02/18/97	
20	K-P	10/31/96		04/28/97	
21	CAE	12/05/96		06/03/97	

Table 4-1  
Blood Specimen PK Times

Blank = Not Obtained

Subj	Date	Time	Day 1																	Day 2				Day 3				Day 4				Day 4			
			Pre	.5hr	1hr	2hr	3hr	4hr	6hr	8hr	10hr	12hr	Pre	12hr	Pre	Day 2	Pre	Day 3	Pre	Day 4	Pre	Day 4	2hr	4hr	Day 4	6hr	8hr	Day 4	12hr						
01	Act:	7:40	8:37	8:57	10:02	11:00	11:57	13:59	16:00	18:03	20:00	07:40	08:05	07:45	10:00	12:02	14:07	15:46	20:00																
01	Schd:	7:30	8:30	9:00	10:00	11:00	12:00	14:00	16:00	18:00	20:00	7:30	7:30	7:30	10:00	12:00	14:00	16:00	20:00																
01	Diff:	10	7	-3	2	0	-3	-1	0	3	0	10	35	15	0	2	7	-14	0																
02	Act:	8:00	8:43	9:13	10:13	11:12	12:20	14:15	16:15	18:20	20:15	08:18	08:18	08:03	10:18	12:18	14:18	16:03	20:05																
02	Schd:	7:45	8:45	9:15	10:15	11:15	12:15	14:15	16:15	18:15	20:15	7:45	7:45	7:45	10:15	12:15	14:15	16:15	20:15																
02	Diff:	15	-2	-2	-2	-3	5	0	0	5	0	33	33	18	3	3	3	-12	-10																
03	Act:	8:17	9:24	9:50	10:56	11:47	12:52	14:50	16:50	19:00	20:50	08:30	08:25	08:13	10:46	12:48	14:50	16:42	20:50																
03	Schd:	8:20	9:20	10:50	11:50	12:50	13:50	15:50	17:50	19:50	21:50	8:20	8:20	8:20	10:50	12:50	14:50	16:50	20:50																
03	Diff:	-3	4	-60	-54	-63	-58	-60	-60	-50	-60	10	5	-7	-4	-2	0	-8	0																
04	Act:	8:34	9:15	9:45	10:40	11:40	12:40	14:40	16:50	18:40	20:40	08:36	09:00	09:45	11:55	13:45	15:55	18:00	20:00																
04	Schd:	8:00	9:00	9:30	10:30	11:30	12:30	14:30	16:30	18:30	20:30	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30																
04	Diff:	34	15	15	10	10	10	10	20	10	10	36	60	105	85	75	85	90	-30																
05	Act:	8:20	9:05	9:25	10:25	11:30	12:25	14:25	16:25	18:25	20:20	08:30	08:35	08:35	11:15	13:07	14:55	17:00	19:00																
05	Schd:	8:00	9:00	9:30	10:30	11:30	12:30	14:30	16:30	18:30	20:30	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30																
05	Diff:	20	5	-5	-5	0	-5	-5	-5	-5	-10	30	35	35	45	37	25	30	-90																
06	Act:	8:45	9:21	9:50	10:50	11:50	13:00	15:00	16:50	19:00	20:45	08:20	09:00	08:58	11:00	12:55	14:55	17:05	21:00																
06	Schd:	8:20	9:20	9:50	10:50	11:50	12:50	14:50	16:50	18:50	20:50	8:20	8:20	8:20	10:50	12:50	14:50	16:50	20:50																
06	Diff:	25	1	0	0	0	10	10	0	10	-5	0	40	38	10	5	5	15	10																
07	Act:	9:25	10:00	10:31	11:35	12:30	13:30	15:30	17:30	19:32	21:30	08:52	09:20	08:58	11:06	13:06	15:10	17:12	21:28																
07	Schd:	9:00	10:00	10:30	11:30	12:30	13:30	15:30	17:30	19:30	21:30	9:00	9:00	9:00	11:30	13:30	15:30	17:30	21:30																
07	Diff:	25	0	1	5	0	0	0	0	2	0	-8	20	-2	-24	-24	-20	-18	-2																
08	Act:	7:53	8:32	9:18	9:56	11:00	12:05	14:00	16:00	18:05	20:10	07:53	08:07	07:55	10:00	12:00	14:00	16:05	20:45																
08	Schd:	7:30	8:30	9:00	10:00	11:00	12:00	14:00	16:00	18:00	20:00	7:30	7:30	7:30	10:00	12:00	14:00	16:00	20:00																
08	Diff:	23	2	18	-4	0	5	0	0	5	10	23	37	25	0	0	0	5	45																
09	Act:	8:14	9:06	9:28	10:15	11:19	12:20	14:20	16:20	18:20	20:26	08:15	08:28	08:15	10:20	12:20	14:20	16:22	20:30																
09	Schd:	7:50	8:50	9:20	10:20	11:20	12:20	14:20	16:20	18:20	20:20	7:50	7:50	7:50	10:20	12:20	14:20	16:20	20:20																
09	Diff:	24	16	8	-5	-1	0	0	0	0	6	25	38	25	0	0	0	2	10																
10	Act:	8:30	9:25	9:45	10:50	11:44	12:40	14:30	16:40	18:40	21:00	08:34	08:55	08:25	10:45	12:50	14:50	16:50	23:40																
10	Schd:	8:10	9:10	9:40	10:40	11:40	12:40	14:40	16:40	18:40	20:40	8:10	8:10	8:10	10:40	12:40	14:40	16:40	20:40																
10	Diff:	20	15	5	10	4	0	-10	0	0	20	24	45	15	5	10	10	10	180																
11	Act:	9:20	9:50	10:20	11:30	12:20	13:20	15:35	17:25	19:20	21:33	09:51	09:05	09:20	11:20	13:05	15:05	17:05	21:10																
11	Schd:	8:50	9:50	10:20	11:20	12:20	13:20	15:20	17:20	19:20	21:20	8:50	8:50	8:50	11:20	13:20	15:20	17:20	21:20																
11	Diff:	30	0	0	10	0	0	15	5	0	13	61	15	30	0	-15	-15	-15	-10																

**Blank = Not Obtained**

Subj	Date Time	Day 1	Day 1	Day 1	Day 1	Day 1	Day 1	Day 1	Day 1	Day 1	Day 2	Day 3	Day 4	Day 4	Day 4	Day 4	Day 4	
		Pre	.5hr	1hr	2hr	3hr	4hr	6hr	8hr	10hr	12hr	Pre	Pre	Pre	2hr	4hr	6hr	8hr
12	Act:	8:18	9:55	9:30	10:30	11:25	12:35	14:30	16:30	18:35	20:10	08:12	08:40	07:50	10:00	12:21	14:20	16:24
12	Schd:	7:45	8:45	9:15	10:15	11:15	12:15	14:15	16:15	18:15	20:15	7:45	7:45	7:45	10:15	12:15	14:15	16:15
12	Diff:	33	70	15	15	10	20	15	15	20	-5	27	55	5	-15	6	5	9
13	Act:	8:55	9:30	10:00	11:00	12:00	13:00	15:04	17:02	19:03	21:00	08:55	09:20	08:55	11:05	13:05	14:55	16:55
13	Schd:	8:30	9:30	10:00	11:00	12:00	13:00	15:00	17:00	19:00	21:00	8:30	8:30	8:30	11:00	13:00	15:00	17:00
13	Diff:	25	0	0	0	0	0	4	2	3	0	25	50	25	5	5	-5	5
14	Act:	8:00	8:50	9:20	10:20	11:20	12:20	14:20	16:20	18:20	20:20	08:25	09:00	08:10	10:28	12:21	14:04	16:09
14	Schd:	8:00	9:00	9:30	11:30	12:30	13:30	15:30	17:30	19:30	21:30	8:00	8:00	8:00	10:30	12:30	14:30	16:30
14	Diff:	0	-10	-10	-70	-70	-70	-70	-70	-70	-70	25	60	10	-2	-9	-26	-21
15	Act:	8:30	9:14	9:50	10:45	11:48	12:50	14:44	16:45	18:35	20:36	08:40	08:41	08:50	10:55	12:55	14:55	16:55
15	Schd:	8:10	9:10	9:40	10:40	11:40	12:40	14:40	16:40	18:40	20:40	8:10	8:10	8:10	10:55	12:55	14:55	16:55
15	Diff:	20	4	10	5	8	10	4	5	-5	-4	30	31	40	0	0	0	-10
16	Act:	7:58	8:40	9:07	10:05	11:05	12:05	14:05	16:10	18:05	20:00	07:55	08:00	08:04	10:04	12:04	14:30	16:30
16	Schd:	7:30	8:30	9:00	10:00	11:00	12:00	14:00	16:00	18:00	20:00	7:30	7:30	7:30	10:00	12:00	14:00	16:00
16	Diff:	28	10	7	5	5	5	5	10	5	0	25	30	34	4	4	30	30
17	Act:	8:29	9:15	9:31	10:31	11:30	12:32	14:30										
17	Schd:	8:00	9:00	9:30	11:30	12:30	13:30	15:30	17:30	19:30	21:30	8:00	8:00	8:00	10:30	12:30	14:30	16:30
17	Diff:	29	15	1	-59	-60	-58	-60										
18	Act:	8:05	9:05	9:37	10:35	11:32	12:34	14:33	16:31	18:35	20:35	08:25	08:40	08:05	10:32	12:35	14:30	16:30
18	Schd:	8:00	9:00	9:30	10:30	11:30	12:30	14:30	16:30	18:30	20:30	8:00	8:00	8:00	10:30	12:30	14:30	16:30
18	Diff:	5	5	7	5	2	4	3	1	5	5	25	40	5	2	5	0	0
19	Act:	8:26	9:02	9:35	10:30	11:32	12:30	14:30	16:55	18:37	20:20	08:35	08:33	08:28	10:43	12:41	14:32	17:00
19	Schd:	8:00	9:00	9:30	10:30	11:30	12:30	14:30	16:30	18:30	20:30	8:00	8:00	8:00	10:30	12:30	14:30	16:30
19	Diff:	26	2	5	0	2	0	0	25	7	-10	35	33	28	13	11	2	30
20	Act:	7:38	8:35	9:05	10:00	11:00	12:00	14:00	16:00	18:03	19:55	08:00	07:47	08:00	10:13	12:08	14:19	16:15
20	Schd:	7:30	8:30	9:00	10:00	11:00	12:00	14:00	16:00	18:00	20:00	7:30	7:30	7:30	10:00	12:00	14:00	16:00
20	Diff:	8	5	5	0	0	0	0	0	3	-5	30	17	30	13	8	19	15
21	Act:	8:12	8:44	9:17	10:16	11:15	12:17	14:16	16:15	18:35	20:00	08:20	08:15	08:00	10:02	12:06	14:00	16:05
21	Schd:	7:45	8:45	9:15	10:15	11:15	12:15	14:15	16:15	18:15	20:15	7:45	7:45	7:45	10:15	12:15	14:15	16:15
21	Diff:	27	-1	2	1	0	2	1	0	20	-15	35	30	15	-13	-9	-15	-10



Table 4-3  
Blood Specimen PK Times

Blank = Not Obtained

Subj	Date Time	Day 5		Day 6		Day 7		Day 7		Day 7		Day 7		Day 7		Day 8		Day 9		Day 10		Day 11		Day 12		Day 13		Day 14		Day 14	
		PRE	Pre	Pre	Pre	Pre	2hr	4hr	6hr	8hr	12hr	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	2hr	4hr	
01	Act:	07:55	07:49	07:56	09:50	11:52	13:58	15:51	20:05	08:03	07:55	07:51	07:58	07:45	07:40	07:58	07:40	07:45	07:30	07:30	07:30	07:45	08:05	08:09	10:55	09:55	12:00				
01	Schd:	7:30	7:30	7:30	10:00	12:00	14:00	16:00	20:00	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:45	8:00	8:09	10:00	12:00					
01	Diff:	25	19	26	-10	-8	-2	-9	5	33	25	21	28	15	10	28	10	28	28	28	28	22	20	24	28	-5	0				
02	Act:	08:05	08:20	08:18	10:02	12:05	14:20	16:07	20:25	08:10	08:17	08:16	08:20	08:07	08:05	08:09	08:05	08:07	08:05	08:05	08:05	08:07	08:05	08:09	10:08	12:10					
02	Schd:	7:45	7:45	7:45	10:15	12:15	14:15	16:15	20:15	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45	10:15	12:15					
02	Diff:	20	35	33	-13	-10	5	-8	10	25	32	31	35	22	20	24	20	22	20	20	22	20	24	28	-7	-5					
03	Act:	08:42	08:40	08:38	10:45	12:43	14:42	16:40	20:55	08:45	08:53	08:49	08:55	08:25	08:34	08:45	08:34	08:25	08:25	08:25	08:25	08:25	08:34	08:45	10:45	12:43					
03	Schd:	8:20	8:20	8:20	10:50	12:50	14:50	16:50	20:50	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	10:50	12:50					
03	Diff:	22	20	18	-5	-7	-8	-10	5	25	33	29	35	5	14	25	14	5	5	5	5	14	25	37	-5	-7					
04	Act:	08:45	08:40	08:40	10:45	12:45	14:45	16:45	20:46	08:40	08:40	08:50	08:47	08:43	08:41	08:37	08:41	08:43	08:43	08:43	08:43	08:43	08:37	10:40	12:40						
04	Schd:	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30						
04	Diff:	45	40	40	15	15	15	15	16	40	40	50	47	43	41	37	41	43	43	43	43	41	37	10	10						
05	Act:	08:25	08:20	08:25	10:25	12:25	14:25	16:21	20:25	08:29	08:25	08:29	08:20	08:25	08:20	08:16	08:20	08:25	08:25	08:25	08:25	08:25	08:16	10:25	12:25						
05	Schd:	20:30	8:00	8:00	10:30	12:30	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30						
05	Diff:	-725	20	25	-5	-5	-5	-9	-5	29	25	29	20	25	20	16	20	25	25	25	25	20	16	-5	-5						
06	Act:	08:55	08:50	09:10	11:10	13:15	15:10	17:10	21:20	08:51	09:10	08:59	08:48	08:48	08:46	08:38	08:46	08:48	08:48	08:48	08:48	08:48	08:38	10:50	12:50						
06	Schd:	8:20	8:20	8:20	10:50	12:50	14:50	16:50	20:50	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	10:50	12:50						
06	Diff:	35	30	50	20	25	20	20	30	31	50	39	28	28	26	18	26	28	28	28	28	26	18	0	0						
07	Act:	09:00	08:54	08:54	11:10	13:04	15:02	17:03	21:30	09:10	09:00	09:25	08:45	09:10	09:14	09:02	09:14	09:10	09:10	09:10	09:10	09:14	09:02	11:07	13:07						
07	Schd:	9:00	9:00	9:00	11:30	13:30	15:30	17:30	21:30	9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00	11:30	14:30						
07	Diff:	0	-6	-6	-20	-26	-28	-27	0	10	0	25	-15	10	14	2	14	10	10	10	10	14	2	-23	-83						
08	Act:	08:03	08:07	07:55	10:00	12:00	14:00	16:00	20:00	08:03	07:55	08:05													12:00						
08	Schd:	7:30	7:30	7:30	10:00	12:00	14:00	16:00	20:00	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	10:00	12:00						
08	Diff:	33	37	25	0	0	0	0	0	33	25	35																			
09	Act:	08:24	08:15	08:15	10:20	12:20	14:15	16:20	20:30	08:18	08:20	08:30	08:13	08:17	08:20	08:19	08:20	08:17	08:17	08:17	08:17	08:20	08:19	10:35	12:34						
09	Schd:	7:50	7:50	7:50	10:20	12:20	14:20	16:20	20:20	7:50	7:50	7:50	7:50	7:50	7:50	7:50	7:50	7:50	7:50	7:50	7:50	7:50	7:50	10:20	12:20						
09	Diff:	34	25	25	0	0	-5	0	10	28	30	40	23	27	30	29	30	27	27	27	27	30	29	15	14						
10	Act:	08:38	08:38	08:35	10:42	12:45	14:45	16:42	22:10	08:45	08:45	09:05	08:30	08:55	08:55	08:36	08:55	08:55	08:55	08:55	08:55	08:55	08:36	10:34	12:45						
10	Schd:	8:10	8:10	8:10	10:40	12:40	14:40	16:40	20:40	8:10	8:10	8:10	8:10	8:10	8:10	8:10	8:10	8:10	8:10	8:10	8:10	8:10	8:10	10:40	12:40						
10	Diff:	28	28	25	2	5	5	2	90	35	35	55	20	45	45	26	45	45	45	45	45	45	26	-6	5						
11	Act:	09:30	09:35	09:15	11:20	13:25	15:10	17:10	21:24	09:38	09:14	09:30	09:59	09:20	09:00	09:25	09:00	09:20	09:20	09:20	09:20	09:20	09:25	11:30	13:31						
11	Schd:	8:50	8:50	8:50	11:20	13:20	15:20	17:20	21:20	8:50	8:50	8:50	8:50	8:50	8:50	8:50	8:50	8:50	8:50	8:50	8:50	8:50	8:50	11:20	13:20						
11	Diff:	40	45	25	0	5	-10	-10	4	48	24	40	69	30	10	35	10	30	30	30	30	30	35	10	11						

Table 4-4  
Blood Specimen PK Times

Blank = Not Obtained

Subj	Date	Day 5	Day 6	Day 7	Day 7	Day 7	Day 7	Day 7	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 14	Day 14
Time	PRE	Pre	Pre	2hr	4hr	6hr	8hr	12hr	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	2hr	4hr
12	Act:	08:13	08:20	08:18	10:12	12:13	14:13	16:15	22:20	08:12	08:17	08:25	08:20	08:30	08:20	08:15	10:25	12:30
12	Schd:	7:45	7:45	7:45	10:15	12:15	14:15	16:15	20:15	7:45	7:45	7:45	7:45	7:45	7:45	7:45	10:15	12:15
12	Diff:	28	35	33	-3	-2	-2	0	125	27	32	40	35	45	35	30	10	15
13	Act:	08:56	08:55	09:00	11:20	13:15	15:15	17:12	21:17	09:00	09:23	10:05	09:05	09:00	08:59	08:55	11:10	13:00
13	Schd:	8:30	8:30	8:30	11:00	13:00	15:00	17:00	21:00	8:30	8:30	8:30	8:30	8:30	8:30	8:30	11:00	13:00
13	Diff:	26	25	30	20	15	15	12	17	30	53	95	35	30	29	25	10	0
14	Act:	08:10	08:15	08:24	10:24	12:16	14:27	16:19	20:43	08:28	08:15	09:05	08:17	08:15	08:20	08:20	10:28	12:20
14	Schd:	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30
14	Diff:	10	15	24	-6	-14	-3	-11	13	28	15	65	17	15	20	20	-2	-10
15	Act:	08:35	08:38	08:44	11:00	12:55	15:00	16:35	20:58	08:45	08:50	09:25	08:38	08:45	08:40	08:28	10:41	12:40
15	Schd:	8:10	8:10	8:10	10:40	12:40	14:40	16:40	20:40	8:10	8:10	8:10	8:10	8:10	8:10	8:10	10:40	12:40
15	Diff:	25	28	34	20	15	20	-5	18	35	40	75	28	35	30	18	1	0
16	Act:	07:36	07:55	08:02	10:06	12:02	14:08	16:02	20:05	08:10	07:45	08:35	07:55	07:50	07:58	08:00	10:05	12:00
16	Schd:	7:30	7:30	7:30	10:00	12:00	14:00	16:00	20:00	7:30	7:30	7:30	7:30	7:30	7:30	7:30	10:00	12:00
16	Diff:	6	25	32	6	2	8	2	5	40	15	65	25	20	28	30	5	0
17	Act:	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30
17	Schd:	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30
17	Diff:																	
18	Act:	08:15	08:11	07:45	10:33	12:34	14:30	16:32	20:28	08:20	08:35	07:45	07:58	08:02	08:25	08:20	10:30	12:35
18	Schd:	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30
18	Diff:	15	11	-15	3	4	0	2	-2	20	35	-15	-2	2	25	20	0	5
19	Act:	08:23	08:02	08:25	12:11	12:35	14:35	16:25	20:45	08:32	08:30	08:25	08:20	08:20	08:23	08:10	10:32	12:34
19	Schd:	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30
19	Diff:	23	2	25	101	5	5	-5	15	32	30	25	20	20	23	10	2	4
20	Act:	08:00	07:58	07:56	09:58	12:08	14:07	16:10	20:05	07:59	08:10	08:12	07:58	07:55	07:55	07:50	10:10	12:03
20	Schd:	7:30	7:30	7:30	10:00	12:00	14:00	16:00	20:00	7:30	7:30	7:30	7:30	7:30	7:30	7:30	10:00	12:00
20	Diff:	30	28	26	-2	8	7	10	5	29	40	42	28	25	25	20	10	3
21	Act:	07:50	07:40	07:56	09:55	12:00	13:58	15:56	20:00	08:01	08:10	08:28	08:10	07:50	07:40	07:47	10:10	12:06
21	Schd:	7:45	7:45	7:45	10:15	12:15	14:15	16:15	20:15	7:45	7:45	7:45	7:45	7:45	7:45	7:45	10:15	12:15
21	Diff:	5	-5	11	-20	-15	-17	-19	-15	16	25	43	25	5	-5	2	-5	-9

Table 5  
Blood Specimen PK Times

Blank = Not Obtained

Subj	Date Time	Day 14		Day 14		Day 15		Day 16		Day 17		Day 18		Day 19		Day 20		Day 21		Day 21		Day 21		Day 21		Day 22	
		6hr	8hr	12hr	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	2hr	4hr	6hr	8hr	12hr	Pre	Pre	Pre	Pre
01	Act:	14:00	16:07	20:10	07:55	08:13	08:20	07:53	07:40	07:50	07:57	08:10	08:12	10:00	12:00	14:00	16:00	19:40	07:50								
01	Schd:	14:00	16:00	20:00	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:45	7:45	10:00	12:00	14:00	16:00	20:00	7:30								
01	Diff:	0	7	10	25	28	23	23	10	20	27	25	27	0	0	0	0	-20	20								
02	Act:	14:23	16:20	20:35	08:13	08:13	08:20	08:20	08:20	08:05	08:10	08:10	08:12	10:15	12:15	14:15	16:15	20:00	08:10								
02	Schd:	14:15	16:15	20:15	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45	10:15	12:15	14:15	16:15	20:15	7:45								
02	Diff:	8	5	20	28	28	35	35	35	20	25	25	27	0	0	0	0	-15	25								
03	Act:	14:56	16:43	20:55	08:52	08:52	08:51	08:51	08:50	08:13	08:50	08:50	08:50	10:53	12:53	14:53	16:59	21:07	09:15								
03	Schd:	14:50	16:50	20:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	10:50	12:50	14:50	16:50	20:50	8:20								
03	Diff:	6	-7	35	32	27	31	31	30	-7	30	30	30	3	3	3	9	17	55								
04	Act:	14:40	16:40	20:40	08:35	08:44	08:45	08:45	08:45	08:57	08:45	08:45	08:39	10:40	12:40	14:55	16:45	20:42	08:45								
04	Schd:	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30	8:00								
04	Diff:	10	10	10	35	44	45	45	45	57	45	45	39	10	10	25	15	12	45								
05	Act:	14:25	16:31	20:30	08:20	08:33	09:15	09:43	08:22	08:25	08:25	08:17	12:25	12:25	12:25	14:25	16:25	20:20	08:24								
05	Schd:	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	12:30	12:30	14:30	16:30	20:30	8:00								
05	Diff:	-5	1	0	20	33	75	103	22	25	25	17	-5	-5	-5	-5	-5	-10	24								
06	Act:	14:58	16:57	20:47	08:39	09:00	08:59	08:39	08:39	08:55	08:35	08:50	12:55	12:55	12:55	14:55	16:55	21:43	08:56								
06	Schd:	14:50	16:50	20:50	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20	10:50	12:50	14:50	16:50	20:50	8:20								
06	Diff:	8	7	-3	19	40	39	19	35	35	15	30	30	125	5	5	5	53	36								
07	Act:	15:07	17:10	21:00	10:10	09:07	09:30	09:05	09:41	09:10	09:12	11:20	13:15	13:15	13:15	14:22	16:47	21:40	09:03								
07	Schd:	15:30	17:30	21:30	9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00	11:30	13:30	15:30	17:30	21:30	9:00								
07	Diff:	-23	-20	-30	70	7	30	5	41	10	12	-10	-15	-15	-15	-68	-43	10	3								
08	Act:																										
08	Schd:	14:00	16:00	20:00	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30	10:00	12:00	14:00	16:00	20:00	7:30								
08	Diff:																										
09	Act:	14:30	16:27	20:00	08:18	08:09	08:19	08:19	08:30	08:25	08:10	10:30	12:30	12:30	12:30	14:25	16:21	20:25	08:10								
09	Schd:	14:20	16:20	20:20	7:50	7:50	7:50	7:50	7:50	7:50	7:50	7:50	7:50	10:20	12:20	14:20	16:20	20:20	7:50								
09	Diff:	10	7	-20	28	19	29	29	40	35	20	10	10	10	10	5	1	5	20								
10	Act:	14:45	16:45	20:30	08:48	08:30	08:41	08:39	09:08	08:50	08:25	10:58	12:45	12:45	12:45	14:58	16:45	20:41	08:38								
10	Schd:	14:40	16:40	20:40	8:10	8:10	8:10	8:10	8:10	8:10	8:10	8:10	8:10	10:40	12:40	14:40	16:40	20:40	8:10								
10	Diff:	5	5	-10	38	20	31	29	58	40	15	18	5	18	5	18	5	1	28								
11	Act:	15:25	17:28	21:20	09:19	08:30	09:28	09:13	09:21	09:20	09:08	11:20	13:15	13:15	13:15	15:15	17:20	21:15	09:12								
11	Schd:	15:20	17:20	21:20	8:50	8:50	8:50	8:50	8:50	8:50	8:50	8:50	8:50	11:20	13:20	15:20	17:20	21:20	8:50								
11	Diff:	5	8	0	29	-20	38	23	31	30	18	0	-5	-5	-5	-5	0	-5	22								

**Table 4-6**  
**Blood Specimen PK Times**

Blank = Not Obtained

Subj	Date Time	Day 14		Day 15		Day 16		Day 17		Day 18		Day 19		Day 20		Day 21		Day 21		Day 21		Day 22	
		6hr	8hr	12hr	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	Pre	2hr	4hr	6hr	8hr	12hr	Pre	
12	Act:	14:30	16:25	20:20	08:22	09:10	08:15	08:14	08:05	08:13	08:00	10:13	12:16	14:22	16:58	20:22	20:22	08:13					
12	Schd:	14:15	16:15	20:15	7:45	7:45	7:45	7:45	7:45	7:45	7:45	10:15	12:15	14:15	16:15	20:15	20:15	7:45					
12	Diff:	15	10	5	37	85	30	29	20	28	15	-2	1	7	43	7	28						
13	Act:	15:10	17:04	21:12	08:52	08:10	09:35	09:30	08:57	09:12	09:05	11:20	13:15	15:19	17:10	21:12	21:12	08:50					
13	Schd:	15:00	17:00	21:00	8:30	8:30	8:30	8:30	8:30	8:30	8:30	11:00	13:00	15:00	17:00	21:00	21:00	8:30					
13	Diff:	10	4	12	22	-20	65	60	27	42	35	20	15	19	10	12	20						
14	Act:	14:20	16:20	20:23	08:25	08:40	08:14	08:22	08:34	08:16	08:50	11:59	12:57	14:55	16:46	21:05	21:05	08:18					
14	Schd:	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30	20:30	8:00					
14	Diff:	-10	-10	-7	25	40	14	22	34	16	50	89	27	25	16	35	18						
15	Act:	14:42	16:40	21:00	08:36	07:45	09:04	08:55	08:35	08:45	08:37	10:45	12:45	14:45	16:45	20:47	20:47	08:37					
15	Schd:	14:40	16:40	20:40	8:10	8:10	8:10	8:10	8:10	8:10	8:10	10:40	12:40	14:40	16:40	20:40	20:40	8:10					
15	Diff:	2	0	20	26	-25	54	45	25	35	27	5	5	5	5	7	27						
16	Act:	14:00	16:00	19:55	07:55	07:45	08:10	08:04	08:04	07:58	07:56	10:10	12:06	14:02	16:05	20:01	20:01	07:58					
16	Schd:	14:00	16:00	20:00	7:30	7:30	7:30	7:30	7:30	7:30	7:30	10:00	12:00	14:00	16:00	20:00	20:00	7:30					
16	Diff:	0	0	-5	25	15	40	34	34	28	26	10	6	2	5	1	28						
17	Act:	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30	20:30	8:00					
17	Schd:	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30	20:30	8:00					
17	Diff:																						
18	Act:	14:35	16:35	20:30	08:20	08:45	08:55	08:17	08:25	08:20	08:15	10:32	12:30	14:30	16:30	20:50	20:50	08:30					
18	Schd:	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30	20:30	8:00					
18	Diff:	5	5	0	20	45	55	17	25	20	15	2	0	0	0	20	30						
19	Act:	14:34	16:33	20:25	08:20	08:23	08:10	08:20	08:25	07:30	08:04	10:30	12:30	14:30	16:36	20:49	20:49	08:20					
19	Schd:	14:30	16:30	20:30	8:00	8:00	8:00	8:00	8:00	8:00	8:00	10:30	12:30	14:30	16:30	20:30	20:30	8:00					
19	Diff:	4	3	-5	20	23	10	20	25	-30	4	0	0	0	6	19	20						
20	Act:	14:00	16:02	20:15	07:55	07:36	07:37	07:58	07:55	07:58	07:55	10:02	12:05	13:55	15:50	20:10	20:10	07:50					
20	Schd:	14:00	16:00	20:00	7:30	7:30	7:30	7:30	7:30	7:30	7:30	10:00	12:00	14:00	16:00	20:00	20:00	7:30					
20	Diff:	0	2	15	25	6	7	28	25	28	25	2	5	-5	-10	10	20						
21	Act:	14:05	16:08	20:20	07:50	08:00	07:57	08:00	07:55	07:58	07:45	10:00	12:00	14:00	16:00	20:00	20:00	08:10					
21	Schd:	14:15	16:15	20:15	7:45	7:45	7:45	7:45	7:45	7:45	7:45	10:15	12:15	14:15	16:15	20:15	20:15	7:45					
21	Diff:	-10	-7	5	5	15	12	15	10	13	0	-15	-15	-15	-15	-15	-15	25					

**Table 4-7**  
**Blood Specimen PK Times**

**Blank = Not Obtained**

Subj	Date Time	Day 29		Day 32		Day 36		Day 39		Day 42		Day 42		Day 42		Day 42		Day 42		Day 43	
		Pre	Act:	Pre	Pre	Pre	Pre	.5hr	1hr	2hr	3hr	4hr	6hr	8hr	10hr	12hr	AM				
01	Act:	09:05	08:00	08:07	08:20	10:05	07:50	08:14	09:10	10:10	12:40	13:05	15:00	17:10	21:35	07:00					
	Schd:	7:30	7:30	7:30	7:30	7:30	8:30	9:00	10:00	11:00	12:00	14:00	16:00	18:00	20:00	7:30					
	Diff:	95	30	37	50	155	-40	-46	-50	-50	40	-55	-60	-50	95	-30					
02	Act:	08:20	07:10	08:55																	
	Schd:	7:45	7:45	7:45	7:45	7:45	8:45	9:15	10:15	11:15	12:15	14:15	16:15	18:15	20:15	7:45					
	Diff:	35	-35	70																	
03	Act:	08:40	08:20	08:27	08:25	08:45	09:45	10:15	11:15	12:15	13:20	15:15	17:15	19:15	21:15	08:45					
	Schd:	8:20	8:20	8:20	8:20	8:20	9:20	10:50	11:50	12:50	13:50	14:50	16:50	18:50	20:50	8:20					
	Diff:	20	0	7	5	25	25	-35	-35	-35	-30	25	25	25	25	25					
04	Act:	09:35	08:50	08:33	08:30																
	Schd:	8:00	8:00	8:00	8:00	8:00	9:00	9:30	10:30	11:30	12:30	14:30	16:30	18:30	20:30	8:00					
	Diff:	95	50	33	30																
05	Act:	09:18																			
	Schd:	8:00	8:00	8:00	8:00	8:00	9:00	9:30	10:30	11:30	12:30	14:30	16:30	18:30	20:30	8:00					
	Diff:	78																			
06	Act:	08:40	08:45	08:36	08:37	08:45	09:30	10:10	11:10	11:50	12:56	15:09	18:05	19:18	21:00	08:30					
	Schd:	8:20	8:20	8:20	8:20	8:20	9:20	9:50	10:50	11:50	12:50	14:50	16:50	18:50	20:50	8:20					
	Diff:	20	25	16	17	25	10	20	20	0	6	19	75	28	10	10					
07	Act:	09:38	19:10	09:20	09:48	10:00	09:43	10:13	11:12	12:01	13:06	15:03	17:13	19:08	21:05	07:39					
	Schd:	9:00	9:00	9:00	9:00	9:00	10:00	10:30	11:30	12:30	13:30	15:30	17:30	19:30	21:30	9:00					
	Diff:	38	610	20	48	60	-17	-17	-18	-29	-24	-27	-17	-22	-25	-81					
08	Act:																				
	Schd:	7:30	7:30	7:30	7:30	7:30	8:30	9:00	10:00	11:00	12:00	14:00	16:00	18:00	20:00	7:30					
	Diff:																				
09	Act:	08:52	09:50	09:50	10:43	08:35	08:50	09:20	10:20	11:33	12:20	14:20	16:20	18:20	20:20	07:40					
	Schd:	7:50	7:50	7:50	7:50	7:50	8:50	9:20	10:20	11:20	12:20	14:20	16:20	18:20	20:20	7:50					
	Diff:	62	120	120	173	45	0	0	0	13	0	0	0	0	0	-10					
10	Act:	08:02	10:45	08:48	11:05	09:10	09:30	09:55	10:50	11:45	12:55	14:55	16:57	18:45	20:48	09:30					
	Schd:	8:10	8:10	8:10	8:10	8:10	9:10	9:40	10:40	11:40	12:40	14:40	16:40	18:40	20:40	8:10					
	Diff:	-8	155	38	175	60	20	15	10	5	15	15	17	5	8	80					
11	Act:	12:35	13:46	08:20		11:53	09:05	09:40	10:10	11:29	12:15	13:10	15:10	17:16	19:17	21:20	09:00				
	Schd:	8:50	8:50	8:50	8:50	8:50	9:50	10:20	11:20	12:20	13:20	15:20	17:20	19:20	21:20	8:50					
	Diff:	225	296	-30		183	15	-10	9	-5	-10	-10	-4	-3	0	10					

**Table 4-8**  
**Blood Specimen PK Times**

Blank = Not Obtained

Subj	Date	Time	Day 25		Day 29		Day 32		Day 36		Day 39		Day 42		Day 42		Day 42		Day 42		Day 42		Day 43	
			Pre	Act	Pre	Act	Pre	Act	Pre	Act	Pre	Act	Pre	Act	Pre	Act	Pre	Act	Pre	Act	Pre	Act	Pre	Act
12	Act:	08:25	08:20	08:25	08:29	08:36	08:21	08:10	08:48	09:19	10:17	11:20	12:26	15:08	16:20	18:20	20:15	09:45						
12	Schd:	7:45	7:45	7:45	7:45	7:45	7:45	7:45	8:45	9:15	10:15	11:15	12:15	14:15	16:15	18:15	20:15	7:45						
12	Diff:	40	35	44	51	36	25	3	4	2	5	11	53	5	5	5	0	120						
13	Act:	08:35	09:01	09:20	09:25	09:30	08:57	09:31	10:30	11:32	12:38	13:37	15:45	17:35	19:31	21:40	09:00							
13	Schd:	8:30	8:30	8:30	8:30	8:30	8:30	9:30	10:00	11:00	12:00	13:00	15:00	17:00	19:00	21:00	8:30							
13	Diff:	5	31	50	55	60	27	1	30	32	38	37	45	35	31	40	30							
14	Act:	07:55	07:37	07:20	07:08	07:30																		
14	Schd:	8:00	8:00	8:00	8:00	8:00	8:00	9:00	9:30	10:30	11:30	12:30	14:30	16:30	18:30	20:30	8:00							
14	Diff:	-5	-23	-40	-52	-30																		
15	Act:	09:00	09:48	10:10	10:40	09:50	08:45	09:14	10:15	11:07	12:14	13:04	15:10	17:07	19:08	21:20	09:07							
15	Schd:	8:10	8:10	8:10	8:10	8:10	8:10	9:10	9:40	10:40	11:40	12:40	14:40	16:40	18:40	20:40	8:10							
15	Diff:	50	98	120	150	100	35	4	35	27	34	24	30	27	28	40	57							
16	Act:	07:32	07:25	07:40	01:18	07:10	07:55	08:40	09:00	10:00	11:05	17:08	14:02	16:00	18:08	20:00	07:59							
16	Schd:	7:30	7:30	7:30	7:30	7:30	7:30	8:30	9:00	10:00	11:00	12:00	14:00	16:00	18:00	20:00	7:30							
16	Diff:	2	-5	10	-372	-20	25	10	0	0	5	308	2	0	8	0	29							
17	Act:																							
17	Schd:	8:00	8:00	8:00	8:00	8:00	8:00	9:00	9:30	10:30	11:30	12:30	14:30	16:30	18:30	20:30	08:30							
17	Diff:																30							
18	Act:	09:48	18:42	18:30			08:05	09:01	09:30	10:30	11:37	12:30	19:36	16:36	18:55	20:41	08:30							
18	Schd:	8:00	8:00	8:00	8:00	8:00	8:00	9:00	9:30	10:30	11:30	12:30	14:30	16:30	18:30	20:30	8:00							
18	Diff:	108	642	630			5	1	0	0	7	0	306	6	25	11	30							
19	Act:	08:35	08:36	09:05	09:00	08:50	08:10	09:05	09:30	10:32	11:30	12:35	14:40	16:38	18:38	20:38	07:00							
19	Schd:	8:00	8:00	8:00	8:00	8:00	8:00	9:00	9:30	10:30	11:30	12:30	14:30	16:30	18:30	20:30	8:00							
19	Diff:	35	36	65	60	50	10	5	0	2	0	5	10	8	8	8	-60							
20	Act:	08:51	12:12	09:15			07:58	08:35	09:05	10:05	11:05	12:05	14:05	16:05	18:05	20:05	08:00							
20	Schd:	7:30	7:30	7:30	7:30	7:30	7:30	8:30	9:00	10:00	11:00	12:00	14:00	16:00	18:00	20:00	7:30							
20	Diff:	81	282	105			77	5	5	5	5	5	5	5	5	5	30							
21	Act:	08:42	09:14	09:04	09:10	09:12	07:50	08:55	09:30	10:28	11:32	12:39	14:32	16:41	18:33	20:40	07:45							
21	Schd:	7:45	7:45	7:45	7:45	7:45	7:45	8:45	9:15	10:15	11:15	12:15	14:15	16:15	18:15	20:15	7:45							
21	Diff:	57	89	79	85	87	5	10	15	13	17	24	17	26	18	25	0							

Table 4-9  
Blood Specimen PK Times

Blank = Not Obtained

Subj	Date	Day 44	Day 45	Day 48	Day 51	Day 54	Day 57	Day 72	Day 180
Time	AM	AM	AM	AM	AM	AM	AM	AM	AM
01	Act:	08:45	08:38	09:18	08:50	08:33	08:50	09:55	10:00
01	Schd:	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30
01	Diff:	75	68	108	80	63	80	145	150
02	Act:								
02	Schd:	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45
02	Diff:								
03	Act:	15:45	09:57	09:00	08:10	08:10	08:28	13:54	09:00
03	Schd:	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20
03	Diff:	445	97	40	-10	-10	8	334	40
04	Act:								
04	Schd:	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00
04	Diff:								
05	Act:								
05	Schd:	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00
05	Diff:								
06	Act:	09:50	09:25	08:48	08:55	08:55	08:40	08:55	08:55
06	Schd:	8:20	8:20	8:20	8:20	8:20	8:20	8:20	8:20
06	Diff:	90	65	28	35	35	20	35	35
07	Act:				12:00	23:40	19:00	18:20	00:44
07	Schd:	9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00
07	Diff:			180	880	600	560	-496	
08	Act:								
08	Schd:	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30
08	Diff:								
09	Act:	11:30		10:25	12:20	14:20	15:05	11:32	15:30
09	Schd:	7:50	7:50	7:50	7:50	7:50	7:50	7:50	7:50
09	Diff:	220	155	155	270	390	435	222	460
10	Act:	15:20			10:30	13:35			
10	Schd:	8:10	8:10	8:10	8:10	8:10	8:10	8:10	8:10
10	Diff:	430			140	325			
11	Act:	09:40	14:03						
11	Schd:	8:50	8:50	8:50	8:50	8:50	8:50	8:50	8:50
11	Diff:	50	313						

Table 7-10  
Blood Specimen PK Times

Blank = Not Obtained

Subj	Date	Day 44	Day 45	Day 48	Day 51	Day 54	Day 57	Day 72	Day 180
	Time	AM	AM	AM	AM	AM	AM	AM	AM
12	Act:	08:34	09:05	08:22	08:40	08:28	08:15	08:56	09:10
12	Schd:	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45
12	Diff:	49	80	37	55	43	30	71	85
13	Act:	09:40	09:42	11:55	10:57	17:00	13:09	13:55	11:50
13	Schd:	8:30	8:30	8:30	8:30	8:30	8:30	8:30	8:30
13	Diff:	70	72	205	147	510	279	325	200
14	Act:								
14	Schd:	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00
14	Diff:								
15	Act:	13:55	16:18	10:30	10:40	11:45	14:07	10:05	11:05
15	Schd:	8:10	8:10	8:10	8:10	8:10	8:10	8:10	8:10
15	Diff:	345	488	140	150	215	357	115	175
16	Act:	09:15							09:30
16	Schd:	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30
16	Diff:	105							120
17	Act:		18:00	09:42	08:45	15:15	17:25	11:40	
17	Schd:	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00
17	Diff:		600	102	45	435	565	220	
18	Act:		18:00	09:42	8:45*	15:15	17:25*	11:40	
18	Schd:	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00
18	Diff:		600	102	1485	435	2005	220	
* Blood drawn on following day									
19	Act:	08:40	09:07	09:50	09:45	09:30	09:15	09:30	
19	Schd:	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00
19	Diff:	40	67	110	105	90	75	90	
20	Act:	08:35	10:58	11:20	13:30				
20	Schd:	7:30	7:30	7:30	7:30	7:30	7:30	7:30	7:30
20	Diff:	65	208	230	360				
21	Act:	08:56	10:50	10:17	14:00	09:45	09:00	09:05	
21	Schd:	7:45	7:45	7:45	7:45	7:45	7:45	7:45	7:45
21	Diff:	71	185	152	375	120	75	80	



Table 5

Subject Number	Drug Screen	Chest X-Ray	Pulmonary Function		TSH $\mu$ U/ml	HIV Screen	HBsAG Screen	HbC Serology Screen	HbCAb Screen
			Screen	Day 42					
Time-->	Screen	Screen			Screen	Screen	Screen	Screen	Screen
01	-	-	Normal	Normal	2.10	-	-		
02	-	-	Normal		0.67	-	-	-	-
03	-	-	Normal	Normal	1.70	-	-	-	-
04	-	-	Normal	Normal	0.11	-		-	
05	-	-	Normal		0.70	-	-	-	-
06	-	-	Normal	Normal	0.44	-	-	-	-
07	-	-	Normal	Normal	0.90	-	-	-	-
08	-	-	Normal		0.60	-	-	-	-
09	-	-	Normal	Normal	1.70	-	-	-	
10	-	-	Normal	Normal	0.80	-	-	-	-
11	-	-	Normal	Normal	1.90	-	-	-	-
12	-	-	Normal	Normal	1.45	-	-	-	-
13	-	-	Normal	Normal		-	-	-	-
14	-	-	Normal		1.27	-	-	-	-
15	-	-	Normal	Normal	2.01	-	-	-	-
16	-	-	Normal	Normal	0.29	-	-	-	+
17	-	-	Normal		4.08	-	-	+	-
18	-	-	Normal	Normal	1.40	-	-	-	-
19	-	-	Normal		0.70	-	-	-	-
20	-	-	Normal	Normal	1.67	-	-	-	-
21	-	-	Normal	Normal	2.36	-	-	-	-
Blank Cell = Not Obtained									
Average					1.34				
Std Dev					0.92				
Max					4.08				
Min					0.11				

Units: mmHg

Table 3a-1  
Vital Signs: Systolic BP

Blank = Not Obtained

Subj \ Day	00	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
01		122	112	112	106	108	116	106	114	118	123	116	134	128	131	126	118
02	132	128	117	122	125	132	112	116	136	137	129	124	130	128	149	132	134
03	132	100	116	107	92	100	101	96	96	95	95	95	118	94	130	106	90
04	112	128	112	108	118	124	138	118	123	122	122	132	132	126	140	126	118
05	139	114	102	114	120	118	104	98	114	108	113	108	110	114	110	104	114
06	124	148	108	127	122	122	122	135	116	114	125	124	124	122	133	126	114
07	154	123	144	118	132	134	136	146	134	133	137	128	140	139	128	158	140
08	122	134	118	106	104	114	108	112	126	115	106						
09	120	126	128	120	128	126	126	112	118	116	108	104	122	122	112	122	108
10	128	124	122	114	118	124	124	136	97	125	114	138	124	119	122	127	128
11	130	116	106	98	97	97	106	110	102	93	89	104	100	90	108	108	113
12	134	104	132	118	116	112	115	121	122	122	116	120	134	129	128	102	130
13	132	112	115	109	108	122	108	120	118	106	92	104	110	108	114	110	116
14	112	106	104	114	116	118	122	118	124	107	100	116	128	109	100	108	102
15	140	110	117	116	106	112	122	114	116	107	110	122	104	114	102	117	106
16	117	92	104	90	90	105	102	96	102	108	94	100	106	104	105	102	98
17	100	128	119														
18		108	114	108	116	106	106	124	94	112	103	106	104	96	110	107	105
19	131	108	128	134	110	115	96	120	125	104	118	96	118	86	127	120	98
20	125	122	125	132	116	122	122	110	122	118	114	104	114	118	126	110	112
21	112	95	83	90	94	82	94	105	106	92	96	99	102	100	92	90	80
Summary:	Systolic BP, mmHg																
Average	126.1	116.6	115.5	112.9	111.7	114.7	114.0	115.7	115.3	112.6	110.2	112.6	118.6	112.9	119.3	115.8	111.8
Std Dev	12.4	13.7	12.7	11.8	11.9	12.5	12.4	13.1	12.2	12.1	13.3	12.9	12.4	14.9	14.9	15.1	15.0
Max	154	148	144	134	132	134	138	146	136	137	137	138	140	139	149	158	140
Min	100	92	83	90	90	82	94	96	94	92	89	95	100	86	92	90	80

Units: mmHg

Table 5a-2  
Vital Signs: Systolic BP

Blank = Not Obtained

Subj \ Day	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33
01	132	122	120			134	136	120	118	138	120	130	126	120	130	128	114
02	122	112	116	120	134	122	113	136	145	138	142	138	124	136	134	142	
03	92	92	90	90	90	96	136	98	90	106	106	91	116	106	98	98	96
04	132	123	110	134	90	140	134	132	124	128	122	132	117	124	132	132	124
05	118	108	109	107	110	122	113	123	120		148	124					
06	108	118	120	122	130	114	124	120	133	116	112	140	122	128	134	132	123
07	128	148	126	136	164	140	138	136	139	144	135	126	122	126	120	120	
08																	
09	108	110	118	116	124	108	132	125	116	114	127	116	140	120	125	116	110
10	120	136	132	119	112	116	125	112	122	135	152	120	132	126	132	124	108
11	98	110	114	127	106	128	110	110	124	116	127	124	130	140	128	126	113
12	100	126	130	124	112	116	116	116	120	134	122	142	135	112	118	132	143
13	114	112	124	107	116	122	122	114	120	122	112	124	122	116	113	124	146
14	122	118	116	118	118	138	135	114	118	123	119	126	114	136	131	124	136
15	98	110	114	116	116	127	143	122	128	130	134	110	133	102	136	124	138
16	92	98	110	110	106	104		98	90	117	129	128	108		116	134	118
17																	
18	96	100	98	114	107	118			108	130	124		142	137		126	124
19	106	106	119	118	100	112	108	124	120	103	116	120	130	146	118	118	128
20	119	116	120	114	114	104	136		116	112	125	124	120	124	124	115	117
21	86	103	105	91	96	103			97	117		113	118			120	115
Summary:																	
Average	110.1	114.1	115.3	115.7	113.6	119.2	126.3	118.8	118.3	123.5	126.2	123.8	125.1	124.9	124.3	124.2	122.1
Std Dev	14.3	13.3	10.3	12.1	17.4	13.1	11.4	11.3	14.4	11.7	12.3	11.9	9.2	12.3	10.1	9.5	13.6
Max	132	148	132	136	164	140	143	136	145	144	152	142	142	146	136	142	146
Min	86	92	90	90	90	96	108	98	90	103	106	91	108	102	98	98	96

Units: mmHg

Table 0a-3  
Vital Signs: Systolic BP

Blank = Not Obtained

Subj \ Day	34	35	36	37	38	39	40	41	42	43	44	45	48	51	54	57	72
01	100	108	108	116	118	116	132	112	116	110	122	126	122	124	128	116	130
02	126	136															
03	94	108	114	110	102	112	100	106	98	98	116	124	106	96	114	113	106
04	134	132	134	118													
05																	
06	130	134	132	124	116	125	120	130	114	130	115	132	134	124	120	132	122
07		126	140	132	108	136	117		142	121				122	108	152	134
08																	
09	112		117	120	115	104	126	108	112	109	114	132	126	115	116	120	115
10	152	119	122	120	115	122	116	104	116	132	128	120		130	124		
11	138	116	130	119	134	125	134	108	94	112	104	118					
12	128	118	106	123	116	126	123	102	134	126	126	106	126	131	128	126	147
13	120	120	120	120	128	112	131	106	106	120	106	122	128	132	118	112	120
14	124	138	154	124	125	144	127										
15	112	123	114	136	130	122	128	122	108	139	110	125	116	124	132	114	138
16	120	111	110	131	115	108	106	97	104	112	116						114
17																	
18	124	138		120	126		130	132	119	128		122	138	112	134	134	136
19	114	119	126	112	123	124	131	119	128	98	122	ND	136	116	116	105	113
20	124	118				130	118	119	92	116	121	126	124	112	132	108	
21	121	124	116			120	134	115	100	107	102	96	134	112	100	123	100
Summary:																	
Average	121.9	122.8	122.9	121.7	119.4	121.7	123.3	112.9	112.2	117.2	115.5	120.8	126.4	119.2	120.8	121.3	122.9
Std Dev	13.6	9.9	13.2	7.1	8.8	10.5	10.0	10.4	14.4	12.2	8.3	10.3	9.5	10.1	10.2	13.2	14.2
Max	152	138	154	136	134	144	134	132	142	139	128	132	138	132	134	152	147
Min	94	108	106	110	102	104	100	97	92	98	102	96	106	96	100	105	100

Units: mmHg

Table 0a-4  
Vital Signs: Systolic BP

Blank = Not Obtained

Subj \ Day	180
01	114
02	
03	112
04	
05	
06	144
07	125
08	
09	116
10	
11	
12	126
13	117
14	
15	140
16	123
17	
18	
19	
20	
21	
Summary:	
Average	124.1
Std Dev	11.3
Max	144
Min	112

Figure 1: SD & Range Charts for Systolic BP, mmHg

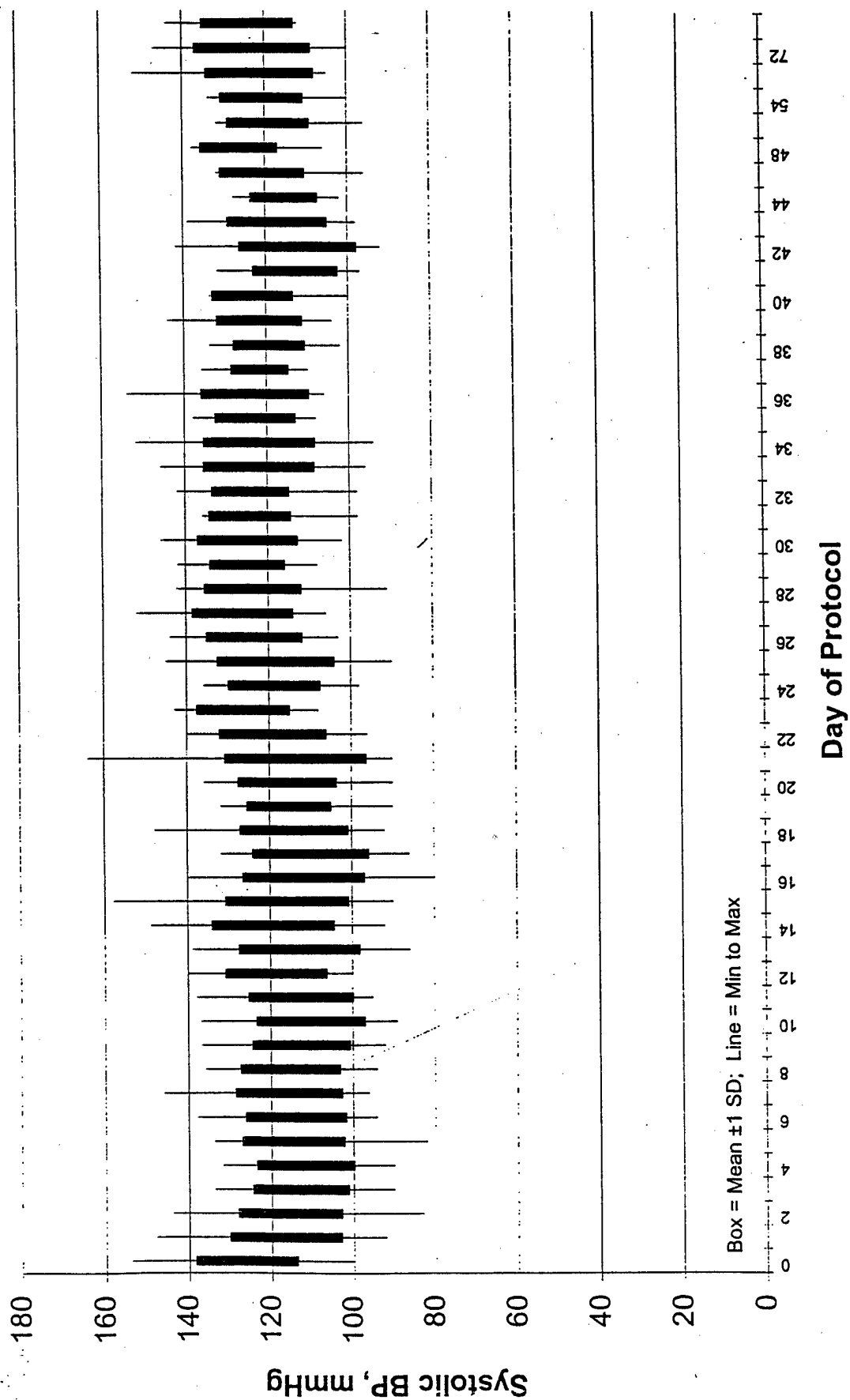
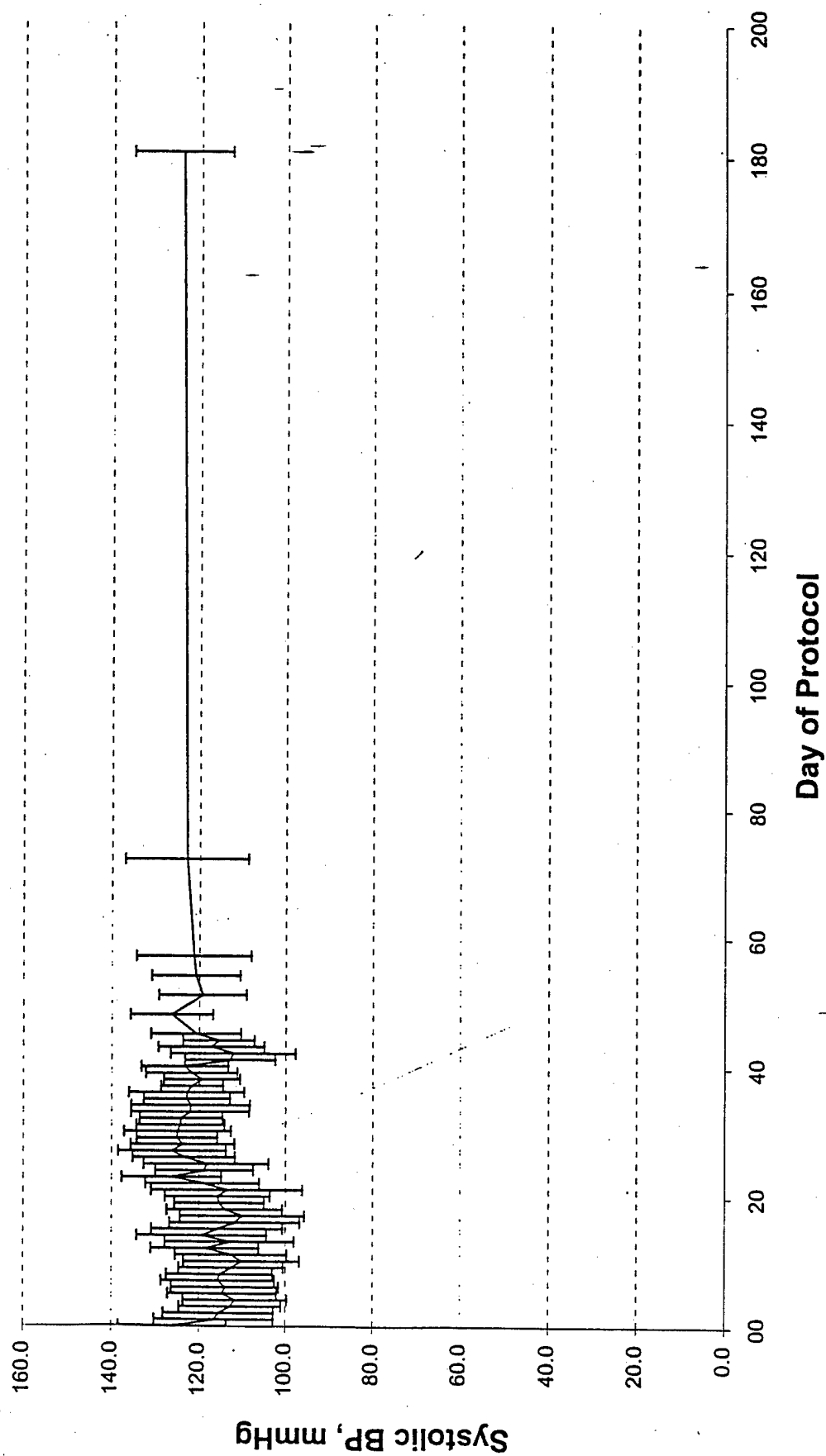


Figure 2: Systolic BP, mmHg



Blank = Not Obtained

Table 6b-1  
Vital Signs: Diastolic BP

Units: mmHg

Subj \ Day	00	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
01	64	74	74	60	68	64	68	60	68	65	61	62	64	74	70	71	74	70	68	70	63
02	72	68	99	68	70	58	56	44	68	63	64	60	74	62	86	84	67	60	50	60	61
03	56	66	54	69	50	46	52	50	52	58	52	42	50	52	46	56	48	46	48	46	56
04	80	72	60	66	58	66	58	60	72	66	68	76	86	82	70	68	64	76	67	76	72
05	68	64	54	58	60	66	56	54	62	58	70	56	60	64	52	58	62	66	60	66	62
06	90	96	74	58	78	71	80	70	68	61	62	84	68	78	70	72	70	70	66	70	68
07	84	60	78	60	64	76	72	68	62	77	58	68	76	78	60	74	64	72	64	72	66
08	70	80	70	64	52	62	59	62	64	53	57										
09	66	68	66	64	72	67	62	66	60	72	55	60	56	50	56	74	52	62	60	62	64
10	68	72	70	62	66	66	70	68	56	73	72	58	69	69	58	72	68	75	70	75	64
11	88	74	59	60	56	56	60	58	72	78	56	60	60	54	76	58	64	62	64	62	74
12	78	78	82	76	72	72	67	85	72	66	66	76	84	78	82	68	80	71	82	71	72
13	64	62	56	57	56	62	46	60	54	56	44	50	48	52	58	52	48	62	60	62	58
14	84	68	66	67	62	64	74	72	70	80	56	64	74	68	54	58	52	72	64	72	75
15	71	68	47	58	64	74	60	63	56	52	50	64	56	54	52	68	46	61	59	61	62
16	60	62	64	60	58	68	60	56	66	68	52	59	64	52	66	60	62	67	60	67	74
17	76	65																			
18	73	61	66	68	64	60	58	64	48	60	54	64	58	50	60	56	60	52	65	52	65
19	80	60	70	77	90	71	56	58	80	76	66	74	72	66	60	64	52	47	66	47	66
20	70	70	71	80	68	88	88	60	66	72	71	64	60	76	64	58	62	66	64	66	72
21	60	54	44	52	56	54	49	57	57	60	58	56	54	55	64	54	48	51	64	58	52
Summary:	Diastolic BP, mmHg																				
average	72.5	68.7	66.2	64.2	64.2	65.6	62.6	61.8	63.7	65.7	59.6	63.0	64.9	63.9	63.4	64.5	60.2	63.6	63.2	63.9	65.6
stdev	9.5	8.9	12.6	7.3	9.4	8.9	10.4	8.7	8.1	8.5	7.7	9.7	10.8	11.3	10.4	8.7	9.7	9.1	7.2	8.7	6.5
max	90	96	99	80	90	88	88	85	80	80	72	84	86	82	86	84	80	76	82	76	75
min	56	54	44	52	50	46	46	44	48	52	44	42	48	50	46	52	46	46	48	46	52



Blank = Not Obtained

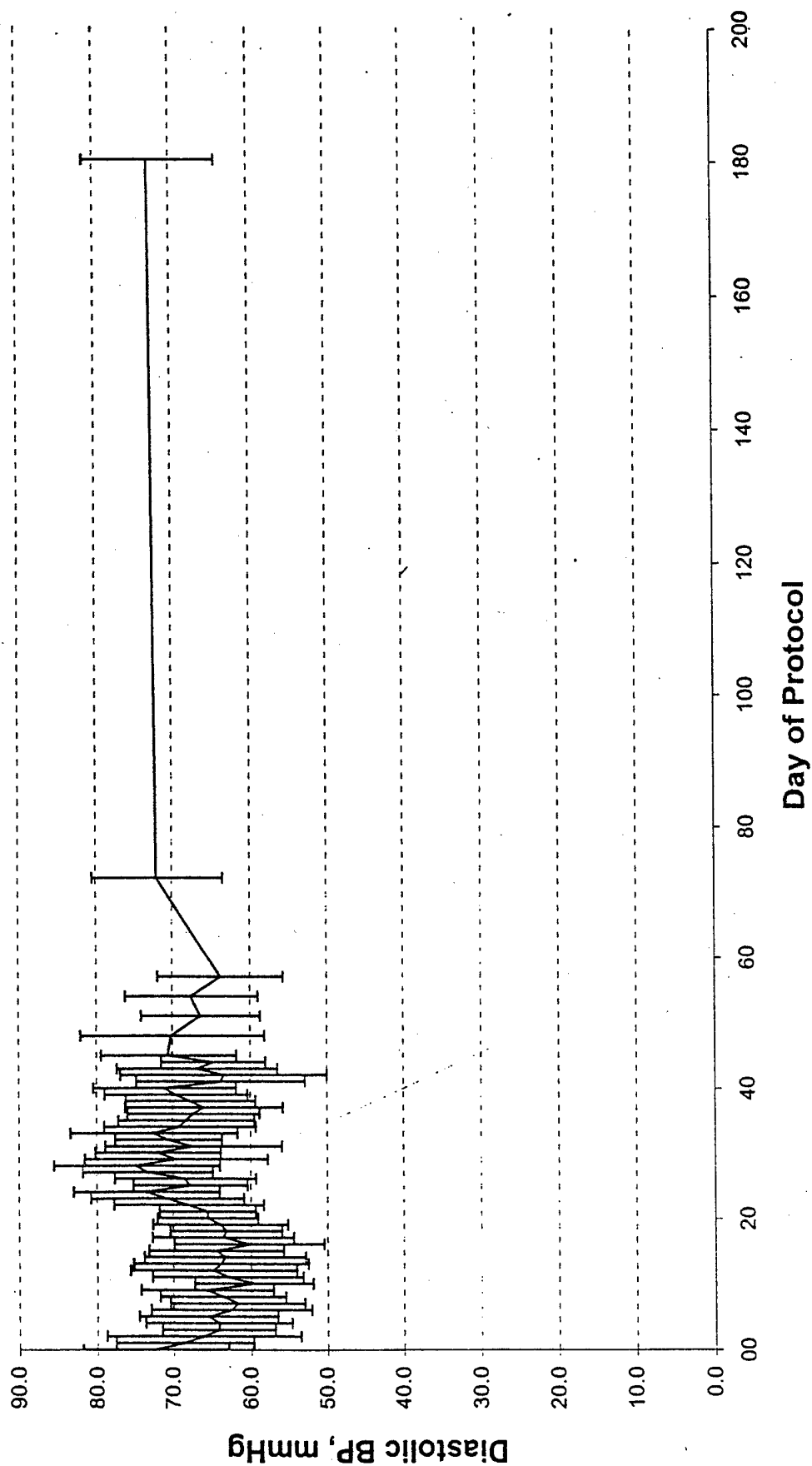
Table 00-2

Vital Signs: Diastolic BP

Units: mmHg

Subj \ Day	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41
01	70	62	72	86	68	64	60	66	70	64	66	72	70	56	54	64	54	64	62	74	62
02	74	74	57	72	74	64	74	78	61	68	67	73		70	63						
03	56	58	54	50	54	50	60	47	52	78	52	58	56	46	68	56	44	56	64	52	54
04	69	86	70	84	84	82	76	84	54	76	76	74	82	82	70	66	68				
05	64	70	76	84	74		72	86												84	
06	70	64	76	82	72	70	72	78	88	73	88	66	79	78	88	80	78	72	76	57	84
07	72	70	66	84	65	62	68	70	54	68	60	66			64	70	64	50	78		
08																				71	58
09	58	60	70	69	68	80	76	97	86	63	56	64	56	54		66	58	64	56	80	54
10	64	71	86	80	74	85	78	70	72	68	55	68	64	74	64	68	72	76	66	78	48
11	64	72	64	76	70	74	79	80	80	80	86	82	70	68	72	78	71	78	70	80	74
12	72	82	66	78	70	74	74	80	80	66	66	79	75	77	80	60	73	66	78	69	58
13	60	58	65	66	66	60	66	64	67	62	57	63	76	58	61	53	66	64	62	71	
14	68	85	89	66	68	80	85	72	65	80	84	72	83	76	65	80	66	67	68	67	54
15	59	61	81	68	72	66	73	70	64	62	56	74	98	70	72	60	60	71	66	64	54
16	70	72		66	58	71	92	86	57		70	84	71	72	65	68	75	65	74		68
17				66																	
18	61	62			54	62	80		90	82		68	80	72	82		58	78		67	80
19	56	70	62	74	72	64	60	70	77	89	72	76	72	72	68	78	84	78	90	87	74
20	76	48	80		62	64	76	78	72	74	68	70	71	74	70				78	70	72
21	63	68			64	61		71	66			63	59	77	56	64			57	68	64
Summary:																					
average	65.6	68.1	70.9	73.6	67.8	68.5	73.4	74.8	69.7	72.1	67.4	70.7	72.6	69.2	68.4	67.4	66.1	67.8	69.7	71.2	63.9
stdev	6.2	9.7	9.9	9.5	7.4	9.2	8.5	10.8	11.9	8.2	11.4	6.9	10.9	9.8	8.8	8.6	10.2	8.4	9.3	9.3	10.9
max	76	86	89	86	84	85	92	97	90	89	88	84	98	82	88	80	84	78	90	87	84
min	56	48	54	50	54	50	60	47	52	62	52	58	56	46	54	53	44	50	56	52	48

Figure 4: Diastolic BP, mmHg



Units: BPM

Table 6c-1  
Vital Signs: Heart Rate

Blank = Not Obtained

Subj \ Day	00	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
01	89	71	70		62	52	63	71	74	60	57	56	71	57	86	58	62	82	76	66	66
02	87	53	98	56	59	58	65	54	63	53	71	58	56	50	66	76	61	56	50	55	61
03	77	64	73	69	51	57	52	61	61	55	56	68	65	87	69	67	67	59	58	57	91
04	80	65	65	64	76	64	64	69	69	67	69	66	84	84	76	76	73	83	98	89	83
05	54	54	50	65	48	59	57	67	54	53	53	62	53	54	48	57	53	50	56	57	60
06	87	69	57	53	64	70	61	59	59	58	61	66	60	67	61	69	57	65	67	66	69
07	62	47	42	47	54	47	67	63	54	66	66	67	61	70	73	79	77	64	69	67	79
08	46	61	62	56	53	55	51	51	54	55	57										
09	52	52	50	53	51	53	47	52	52	52	55	50	46	50	48	57	48	57	47	49	47
10	83	74	71	74	83	74	76	69	83	74	70	74	64	63	93	66	66	59	91	89	66
11	107	93	75	64	66	65	64	67	63	73	61	65	61	58	61	60	63	67	65	71	86
12	60	89	67	60	61	66	65	64	65	79	66	60	63	67	60	81	67	71	69	69	70
13	64	43	42	46	43	46	49	46	48	48	44	45	44	42	43	46	50	43	45	44	41
14	60	45	58	48	46	48	48	46	45	50	46	48	48	50	45	46	54	48	50	46	48
15	70	65	77	64	58	69	59	59	59	58	62	59	64	60	57	48	53	54	71	60	60
16	82	85	70	71	74	69	65	70	71	73	70	69	63	79	70	67	79	67	69	70	67
17	67	76																			
18	70	64	60	73	64	63	61	79	62	64	58	78	60	66	60	60	66	62	66	66	67
19	70	56	67	65	70	76	67	74	67	81	60	77	69	73	66	87	64	63	69	70	59
20	62	54	65	64	52	63	63	63	55	92	90	59	60	67	66	60	61	59	60	62	69
21	71	70	59	70	56	69	63	61	70	66	57	63	60	57	78	59	59	66	67	58	74
Summary	Heart Rate, BPM																				
Average	71.5	64.0	64.2	60.7	59.7	60.7	60.2	62.3	60.9	63.7	61.7	62.6	60.7	63.6	63.8	64.4	62.3	61.6	65.3	64.1	66.1
Std Dev	14.6	13.9	12.9	8.6	10.5	9.0	7.5	9.0	9.3	11.8	10.0	9.0	9.2	12.0	13.4	11.8	8.6	10.2	13.6	12.0	13.0
Max	107	93	98	74	83	76	76	79	83	92	90	78	84	87	93	87	79	83	98	89	91
Min	46	43	42	46	43	46	47	46	45	48	44	45	44	42	43	46	48	43	45	44	41

Units: BPM

Table uc-2  
Vital Signs: Heart Rate

Blank = Not Obtained

Subj \ Day	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41
01	71	71	77	96	80	91	61	71	67	60	66	70	62	65	65	62	73	73	69	93	62
02	65	81	52	66	71	69	85	77	79	87	88	114		107	85						
03	60	57	70	48	57	60	59	71	63	58	58	69	64	63	67	62	62	61	73	85	64
04	83	92	110	89	93	93	91	100	71	83	74	85	81	83			78				
05	57	53	66	73	53		76	63													
06	64	69	83	87	87	89	69	88	89	73	77	70	76	83	73	70	76	85	74	69	96
07	89	70	91	89	70	93	85	74	60	77	61	69			66	53	66	49	76	50	
08																					
09	46	50	63	60	74	96	60	83	63	61	65	79	57	63		56	62	54	50	60	59
10	70	85	81	83	70	104	107	76	89	91	91	73	81	91	93	63	81	79	54	87	60
11	63	109	71	83	73	87	79	67	77	74	71	74	67	79	76	74	74	74	76	83	74
12	66	70	71	83	83	89	77	85	74	70	64	81	66	81	71	65	69	70	89	76	93
13	45	48	69	74	62	65	44	50	53	74	48	63	81	59	56	56	62	55	54	63	50
14	50	57	83	57	60	64	59	56	62	56	53	53	55	70	52	79	50	55	53	53	
15	52	61	81	85	74	71	79	64	74	79	76	81	94	73	92	79	69	83	83	85	83
16	74	85		104	85	101	81	81	87		79	70	77	70	73	81	83	77	71	89	91
17																					
18	73	77			85	89	89		96	87		81	91	83	104		85	89		79	87
19	56	79	67	70	70	66	74	64	79	89	66	70	70	79	69	73	73	69	81	64	64
20	70	63	66		58	62	63	60	63	61				61	53				61	51	54
21	60	62			61	58		55	58			62	69	77	61	62			57	65	61
Summary																					
Average	64.1	70.9	75.1	77.9	72.5	81.7	74.3	72.4	73.3	73.8	69.1	75.1	73.0	75.6	73.0	67.2	70.9	69.5	68.9	72.5	72.1
Std Dev	11.7	15.7	13.4	15.0	11.4	15.5	15.0	13.0	12.3	11.8	12.0	13.0	11.6	12.3	14.9	9.2	9.4	12.8	12.4	14.4	15.7
Max	89	109	110	104	93	104	107	100	96	91	91	114	94	107	104	81	85	89	89	93	96
Min	45	48	52	48	53	60	44	50	53	56	48	53	55	59	52	53	50	49	50	50	50

Units: BPM

Table cc-3  
Vital Signs: Heart Rate

Blank = Not Obtained

Subj \ Day	42	43	44	45	48	51	54	57	72	180
01	63	64	59	61	64	53	69	69	77	76
02										
03	87	79	74	74	81	81	66	66	73	62
04										
05										
06	59	52	59	71	77	67	77	59	61	77
07	69	46				71	70	89	73	50
08										
09	50	45	69	52	51	60	57	68	53	69
10	66	65	79	87		79	93			
11	64	62	73	89						
12	74	74	60	62	76	85	66	85	69	70
13	45	50	60	69	53	61	61	52	61	65
14										
15	60	71	65	76	76	70	73	58	107	93
16	63	73	91							
17										
18	59	59	83	83	76	83	91	85	89	
19	76	76	69		85	81	79	76	59	
20	57	62	61	61	58	73	56	59		
21	61	74	77	69	77	91	74	70	62	
Summary										
Average	63.7	62.7	69.4	71.4	69.7	72.0	71.5	69.6	72.2	70.3
Std Dev	10.3	11.2	10.1	11.3	11.7	11.1	11.4	12.0	15.5	12.6
Max	87	79	91	89	85	85	93	89	107	93
Min	45	45	59	52	51	53	56	52	53	50

Figure 5: SD &amp; Range Charts for Heart Rate, BPM

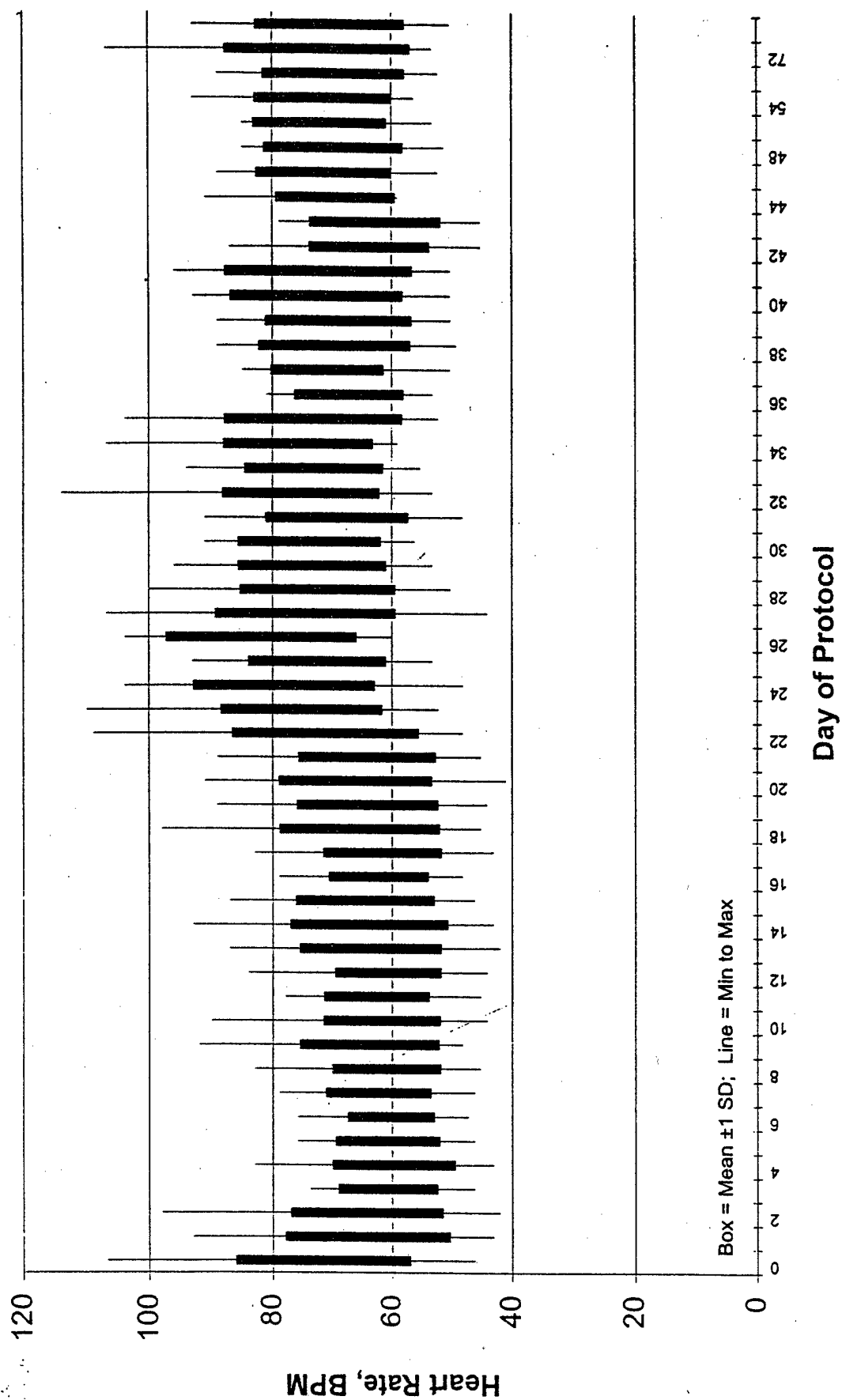
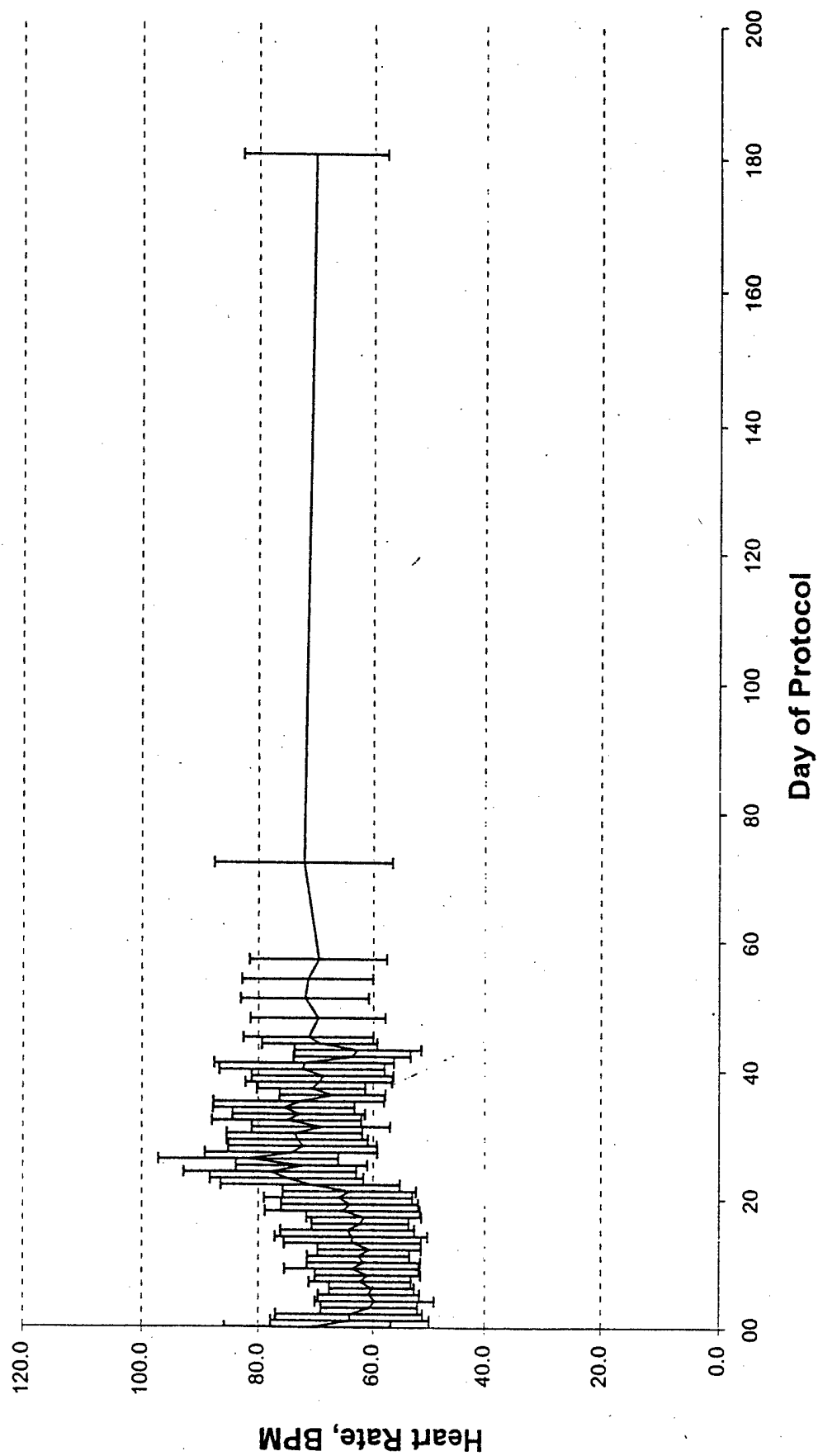


Figure 6: Heart Rate, BPM



Units: °C

Table 6d-1  
Vital Signs: Body Temperature

Blank = Not Obtained

Subj \ Day	00	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
01	37.0	35.8	36.1	35.6	35.3	35.7	36.2	36.2	35.6	36.1	36.2	35.7	35.6	35.5	36.1	35.5	36.1	36.5	36.0	35.9	36.4
02		36.4	36.2	35.8	38.7	35.5	36.2	36.3	36.6	36.8	37.1	36.7	36.3	36.2	35.4	36.2	35.5	35.5	35.6	36.2	35.5
03	36.6	36.6	36.6	36.1	36.4	36.7	36.6	36.4	37.0	36.8	37.1	36.7	36.3	36.6	36.1	36.7	36.7	37.0	37.0	36.7	36.8
04	36.9	36.7	36.7	36.4	36.7	36.7	36.5	36.8	36.7	36.8	36.5	36.7	36.8	36.9	36.9	36.7	36.9	36.5	37.8	37.7	36.6
05	36.3	36.1	36.2	36.7	35.8	35.9	36.2	36.4	36.1	36.2	36.2	36.0	36.3	36.3	36.3	36.0	36.0	35.9	36.5	35.9	36.4
06	37.0	36.6	36.0	35.9	34.4	36.0	36.0	36.2	35.8	36.3	35.8	36.3	35.9	35.9	35.9	36.0	36.3	36.8	36.6	36.7	36.3
07	36.2	36.3	35.4	35.9	36.7	35.9	36.0	36.2	35.8	36.3	35.8	36.3	35.9	35.9	35.9	36.0	36.3	36.8	36.6	36.7	36.3
08	36.6	36.0	36.3	36.1	35.9	36.1	36.1	36.0	36.0	36.4	36.2										
09	36.6	36.1	36.6	36.0	36.1	36.0	36.2	36.2	36.2	36.2	36.4	36.8	36.8	36.7	35.5	36.7	36.9	36.9	36.9	38.1	36.5
10	37.0	36.7	36.9	36.7	36.9	36.9	37.4	37.1	36.3	36.4	36.9	36.8	36.8	36.2	36.3	36.3	36.0	36.2	35.8	36.4	36.2
11	36.8	37.6	37.3	36.6	36.6	36.0	36.7	36.4	36.6	36.7	36.7	36.3	36.4	36.2	36.3	36.3	36.0	36.2	36.4	36.1	35.5
12	35.6	35.6	35.5	35.6	35.6	35.8	35.0	35.6	36.0	36.3	35.9	35.7	36.0	35.6	35.5	36.4	35.6	36.2	35.5	35.8	35.8
13	36.9	36.2	36.0	35.9	36.1	36.0	35.9	36.0	36.2	36.2	35.5	35.9	35.7	35.7	36.1	36.6	36.4	36.6	36.5	36.5	36.5
14	36.5	36.6	36.4	36.3	36.4	36.4	36.3	36.3	36.2	36.4	36.5	36.5	36.5	36.1	36.5	36.6	36.4	36.6	36.0	36.0	35.5
15	35.6	35.6	36.2	35.8	36.0	35.6	35.4	36.0	36.2	36.1	35.7	35.5	35.7	35.7	35.7	35.3	36.0	36.0	36.0	36.0	36.2
16	36.5	36.7	36.2	36.0	36.4	36.3	35.9	36.4	36.3	36.4	36.2	36.0	36.5	36.5	36.2	36.0	36.0	36.5	36.1	36.3	36.2
17	37.0	36.1																			
18	36.4	36.0	36.2	36.1	36.0	36.2	36.7	36.1	36.1	36.0	36.0	36.1	36.1	36.1	36.4	36.2	36.4	36.1	36.4	36.6	36.1
19	37.0	36.5	36.3	36.2	36.3	36.3	36.3	36.3	36.0	36.4	35.6	36.4	36.1	36.0	36.2	36.5	37.0	35.2	35.8		36.2
20	36.8	36.2	36.2	36.2	36.3	36.1	36.1	36.3	36.4	36.4	36.2	36.4	36.0	36.0	36.4	36.4	36.0	36.1	36.4	37.1	36.4
21	36.7	35.8	36.5	36.3	36.1	36.3	35.9	36.4	35.8	36.1	36.4	36.1	35.9	36.1	35.8	35.9	35.8	36.4	36.6	35.9	36.0
Summary	Body Temperature, °C																				
Average	36.6	36.3	36.3	36.1	36.2	36.1	36.2	36.3	36.2	36.4	36.2	36.2	36.1	36.1	36.1	36.2	36.2	36.3	36.3	36.5	36.2
Std Dev	0.4	0.5	0.4	0.3	0.8	0.4	0.5	0.3	0.3	0.2	0.5	0.4	0.4	0.4	0.4	0.4	0.5	0.5	0.6	0.6	0.4
Max	37.0	37.6	37.3	36.7	38.7	36.9	37.4	37.1	37.0	36.8	37.1	36.8	36.8	36.9	36.9	36.7	37.0	37.0	37.8	38.1	36.8
Min	35.6	35.6	35.4	35.6	34.4	35.5	35.0	35.6	35.6	36.0	35.5	35.5	35.6	35.5	35.4	35.3	35.0	35.2	35.5	35.8	35.5



Units: °C

Table 6d-2  
Vital Signs: Body Temperature

Blank = Not Obtained

Subj \ Day	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41
01	36.1	35.6	36.7	36.2	36.3	35.9	36.1	36.5	36.0	35.2	36.7	36.3	36.0	35.4	34.6	36.0	36.3	35.2	36.6	35.6	35.3
02	35.1	35.3	35.7	36.0	35.9	36.1	36.3	36.7	36.5	36.5	36.4	38.2		38.3	36.9						
03	36.8	36.6	36.7	36.4	36.7	35.8	36.5	36.6	36.7	36.4	36.2	36.7	36.2	36.8	36.5	36.6	36.5	36.7	35.7	36.6	36.1
04	37.0	36.7	37.1	36.7	37.2	37.0	36.7	37.2	36.8	36.9	36.7	36.8	37.0	36.9	36.6	36.6	36.8				
05	36.1	36.1	34.8	35.3	35.0		35.7	35.8													
06	36.6	36.4	36.4	36.7	36.1	37.0	37.0	36.5	37.0	36.6	36.7	36.7	37.0	37.1	36.0	35.9	36.9	36.9	36.4	36.0	36.9
07	36.6	36.7	36.4	35.5	36.2	36.6	36.9	39.9	36.7	35.5	36.3	36.7			36.6	36.5	36.6	35.6	36.2	35.6	
08																					
09	36.3	36.0	36.3	37.0	36.4	35.8	36.0	36.4	36.2	36.2	36.4	36.1	36.5		36.3	36.7	36.5	36.2	36.2	36.2	36.1
10	36.9	36.5	36.2	36.1	36.0	35.9	37.0	36.8	36.9	35.8	36.4	36.9	36.6	36.4	35.5	36.4	36.6	36.3	36.6	36.9	36.7
11	36.3	36.1	35.3	36.3	35.7	35.8	36.1	36.0	36.0	36.3	36.4	36.1	36.7	36.9	36.1	36.4	36.6	35.5	36.2	36.6	36.7
12	36.0	36.2	36.3	35.7	36.4	36.7	35.7	35.8	36.1	36.0	36.4	35.5	36.6	35.8	36.0	35.8	35.4	35.6	36.2	35.4	35.2
13	35.9	36.3	35.0	36.3	34.8	35.6	35.0	39.7	34.8	34.8	35.3	39.5	35.0	33.2	35.5	35.1	36.2	36.0	35.5	34.8	35.2
14	36.5	36.0	37.2	36.1	36.2	36.5	35.9	36.4	35.5	35.8	36.1	36.9	36.4	35.4	36.5	36.7	36.3	35.7	36.1	36.6	
15	35.3	35.0	35.7	35.8	35.3	36.0	36.0	35.8	36.0	34.7	34.6	36.1	35.3	34.1	35.1	35.1	35.4	36.0	35.0	35.4	36.0
16	36.3	36.0		36.7	36.7	36.8	35.8	36.2	36.3		36.1	36.2	36.9	36.1	35.9	36.1	36.2	36.0	36.1	35.8	36.3
17																					
18	36.2	36.5			35.8	36.6	36.8		36.5	35.8		36.7	36.6	36.1	36.7		36.5	35.3		36.8	36.3
19	36.0	35.4	35.7	35.4	34.4	36.4	36.3	35.5	36.3	36.5	36.7	36.3	36.7	36.1	36.1	36.7	36.4	36.2	36.3	36.3	36.4
20	36.3	36.3	36.6		36.3	36.5	35.5	36.7	36.8	36.0	36.6	36.5	36.1	36.0	36.0				36.2	36.4	36.1
21	36.0	36.2			36.1	36.0	36.1	36.3				36.1	36.3		36.0	36.3			35.7	35.6	35.8
Summary																					
Average	36.2	36.1	36.1	36.1	36.0	36.3	36.2	36.7	36.3	35.9	36.3	36.7	36.4	36.0	36.1	36.2	36.3	35.9	36.1	36.0	36.1
Std Dev	0.5	0.5	0.7	0.5	0.7	0.4	0.5	1.2	0.6	0.6	0.6	0.9	0.6	1.2	0.6	0.5	0.4	0.5	0.4	0.6	0.5
Max	37.0	36.7	37.2	37.0	37.2	37.0	37.0	39.9	37.0	36.9	36.7	39.5	37.0	38.3	36.9	36.7	36.9	36.9	36.6	36.9	36.9
Min	35.1	35.0	34.8	35.3	34.4	35.6	35.0	35.5	34.8	34.7	34.6	35.5	35.0	33.2	34.6	35.1	35.4	35.2	35.0	34.8	35.2

Units: °C

Table 6d-3  
Vital Signs: Body Temperature

Blank = Not Obtained

Subj \ Day	42	43	44	45	48	51	54	57	72	180
01	36.0	36.1	35.4	35.1	36.0	35.8	36.1	36.3	35.8	36.0
02										
03	36.9	37.0	35.7	35.9	36.5	37.0	36.6	36.0	36.2	36.7
04										
05										
06		36.2	36.4	36.4	36.6	36.3	36.6	36.4	36.7	36.7
07	37.2	35.8				36.4	36.1	37.1	36.7	36.4
08										
09		36.1	36.3	36.5	36.2	36.7	36.2	36.5	36.2	36.8
10	36.7	36.6	36.4	36.6		36.7	36.1			
11	36.4	36.5	36.4	36.6						
12	35.8	35.8	35.6	35.8	36.0	35.0	35.5	35.0	36.0	35.3
13	36.0	35.0	35.5	36.0	36.6	35.9	35.8	36.6	36.6	35.4
14										
15	36.1	36.0	36.4	35.2	35.8	35.5	36.5	36.2	36.7	35.1
16	36.2	36.6	36.9						36.5	36.7
17										
18		36.1		36.1	36.7	36.1	36.4	36.7	35.7	
19		36.3	36.4		37.0	36.1	36.4	35.9	36.6	
20	36.4	36.6	36.3	36.0	36.5	36.8	36.8	36.1		
21	36.0	36.6	36.4	36.3	36.5	37.2	36.2	36.4	36.2	
Summary										
Average	36.3	36.2	36.2	36.0	36.4	36.3	36.3	36.3	36.3	36.1
Std Dev	0.4	0.5	0.5	0.5	0.4	0.6	0.4	0.5	0.4	0.7
Max	37.2	37.0	36.9	36.6	37.0	37.0	36.8	37.1	36.7	36.8
Min	35.8	35.0	35.4	35.1	35.8	35.0	35.5	35.0	35.7	35.1

Figure 7: SD &amp; Range Charts for Body Temperature, °C

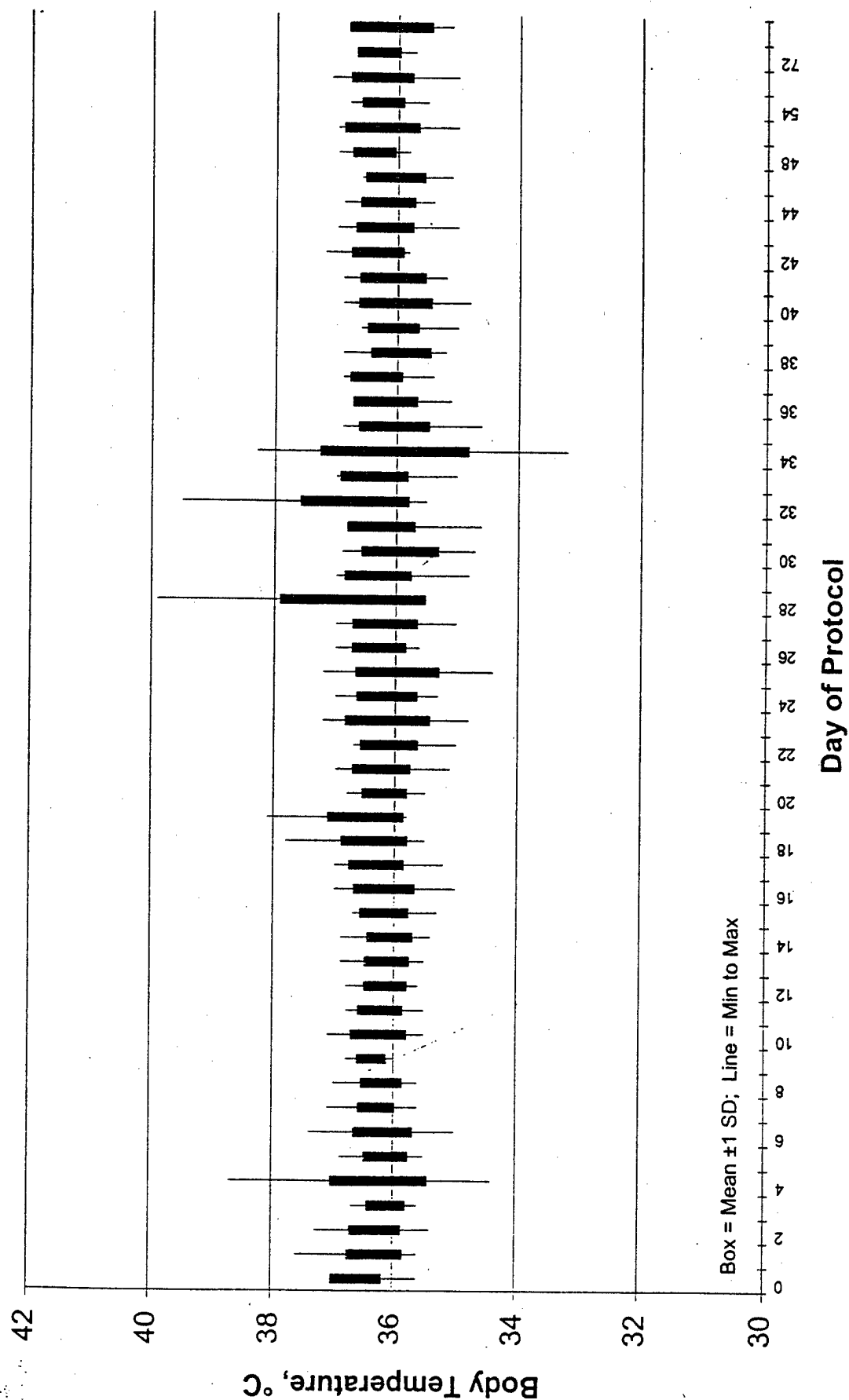
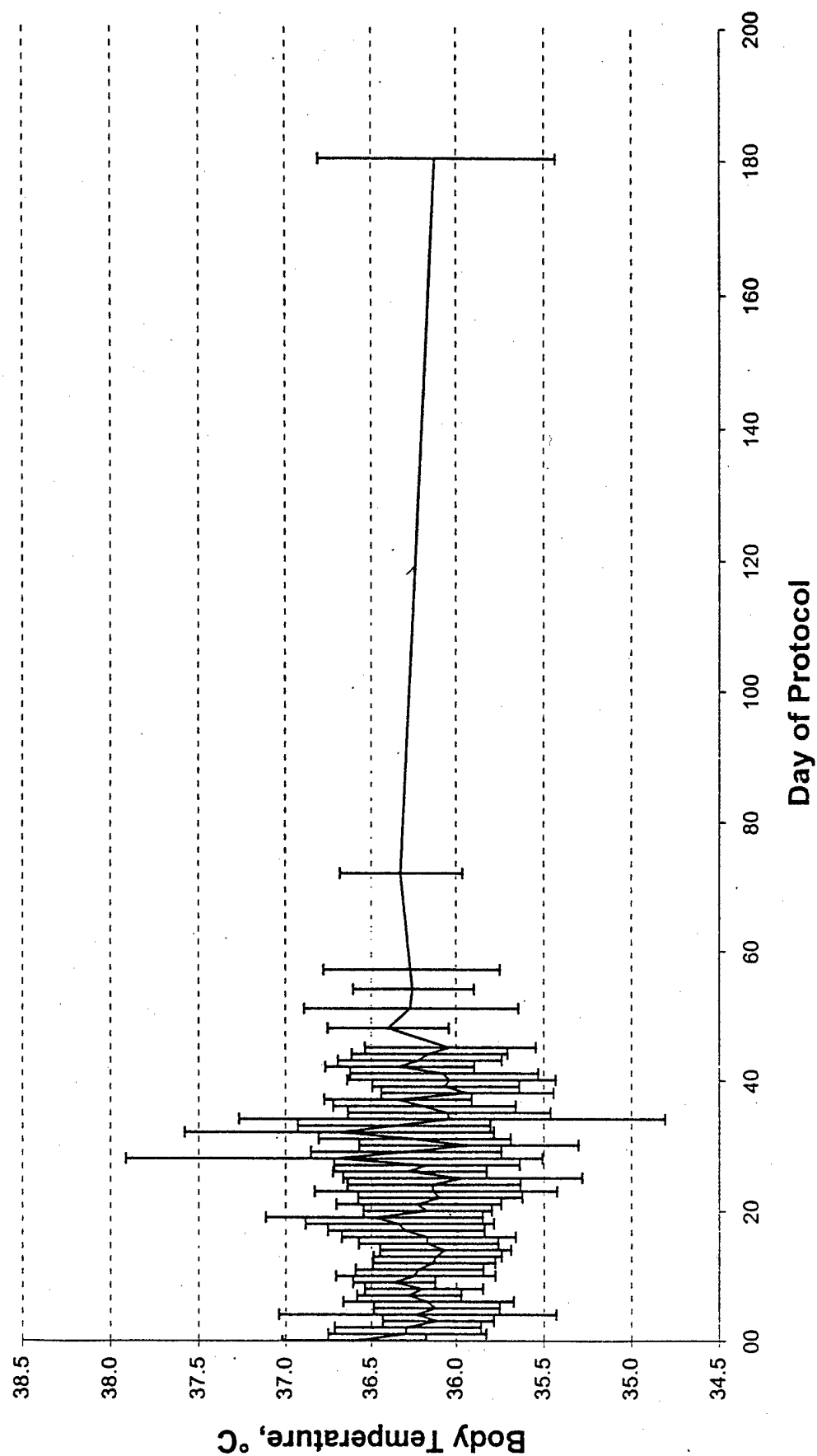


Figure 8: Body Temperature, °C



Units: Pounds

Table 6e-1  
Body Weight

Blank = Not Obtained

Subj \ Day	00	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
01																	
02																	
03																	
04									154	155	156	157	158	159	159	159.5	158
05									148	147	148	147	145	147	146	146	146
06									169	170	169	168	170	170	169.5	170	169
07									169	172	174	172	173	173	173	179	181
08									125	125	125						
09									165	165.5	169	165	167	175	164	164	164
10									164	164	164	164	165	166	165	165	165
11									146	146	146	146	146	146	148	149	148.5
12									185	184	183	184	184	184	182	182	183
13									140	140	140	140	140	141	141	141	140
14									162	163	163	162	162	162	162	164	163
15									152	152	152	152	153	152	152	152	152
16									165	165	165	165	165	167	166	166	167.5
17																	
18									148	148	150	144	150	150	152	151	152
19									173	177	173	171	172	172	172	172	171
20									173	174	173	174	174.5	175	176	175	175
21									202	203	200	203	204	202	202	202	202
Summary:	Body Weight, Lb																
Average	206.0	162.6	161.0	161.6	160.6	161.7	162.3	161.8	161.2	161.8	161.8	163.4	164.3	165.1	164.3	164.8	164.8
Std Dev		18.6	18.0	18.2	18.6	18.4	18.5	18.4	17.9	18.4	17.6	16.2	16.2	15.9	15.3	15.5	15.8
Max	206	202	200	200	199	200	200	200	202	203	200	203	204	202	202	202	202
Min	206	127	125	125	125	125	126	125	125	125	125	140	140	141	141	141	140

Units: Pounds

Table 6e-2  
Body Weight

Blank = Not Obtained

Subj \ Day	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
01													150	148	151	152
02												221	214	214	216	
03													148	148	148	148
04	160	159	159	159	159	159	163.5	169	169	163	162	163	163	148	148	148
05	146	146	144	145	144	145	148	150	150			150				
06	170	170	170.5	172	173.5	171	171	172	175	174	173.5	173	172	172	172	172
07	179	178.5	178.5	181.5	179	178	179	181.5	182	180	176	177	178	180	180	178
08																
09	164	166	165	167	166	166	169	166	163	162	164	164	164	167	167.5	168
10	165	168	166	168	169	168	168	168	168	168	168	168	168	167	170	169
11	147	147	147	147	148	147	150	148	150	148	150	150	154	152	149	150
12	183.7	185	183	182	183	180	185	185	184	184	184	184	182	182	184	183
13	140	140	141	140	140	142	140	141	141	142	142	140	141	142	140	139.5
14	166	165	163	164	164	167	168	167	167	167	165	165	165	166	165	167
15	152	152	152	153	153	153	154	154	154	156	157	154	158	156	156	151
16	167	167	167	168	168	168		168	168	170	170	170	171		170	171
17																
18	152	151	152	152	152	153			152	152	151		151.5	151		152.5
19	171	172	173	173	172	171	172	179	176	178	175	178	177	180	176	178
20	175	178	178	177	179	180		180	182.5	181	181	180	177	180	181	179
21	201	202	204	200	202	202			204	204			204	205		205
Summary:																
Average	164.9	165.4	165.2	165.5	165.7	165.6	164.0	166.3	167.8	168.6	165.6	169.1	168.8	168.1	167.1	165.4
Std Dev	15.7	16.2	16.4	15.8	16.2	15.6	13.4	13.5	16.2	15.9	12.3	19.0	18.7	20.5	18.9	16.9
Max	201	202	204	200	202	202	185	185	204	204	184	221	214	214	216	205
Min	140	140	141	140	140	142	140	141	141	142	142	140	141	142	140	140

Blank = Not Obtained

Table 6e-3  
Body Weight

Units: Pounds

Subj \ Day	33	34	35	36	37	38	39	40	41	42	43	44	45	48	51	54	57
01	150	150	149.5	150	150												
02	206	206				151	149.5	150	149	149	148	149	152	149	148	147	147
03	151	150	150	150	149.7	151	152	151.5	151	146	144	150	150	150	148	150	150
04	151	150	163	164	162												
05																	
06	173	171	170	171	172	172.5	172	172	169	169	172	172	172.5	172	171	170	173
07																	
08																	
09	168	166															
10	169	168	168	165	168	167	165	165	165	167	167	169	168		170	169	
11	153	151	151	151	149	150	150	148	144	148	150	144	151				
12	184	183	183	183	182	183	183	182	184	184	182	183	184	183	184.5	183	184
13	139	139	141	141	140	139	145	139	139	136	137	136	136	141	141	137	138
14	165	165	164	167	168	168	168	166	168								
15	151	156	156	160	159	155	158	156	159	156	158	161	158	158	158	164	160
16		174	172		171	170	171	171	171	169	168	169					
17																	
18	153	155	153		151	145		152	150	150			154	152	150	150	152
19	176	175		177	178	176	179	178	175	173	173	177	181	174	179	174	178
20	177	178				182	180	180		179	179	181	180	181	182	180	
21	207	208	208	206			205	206	204	204		204	204	205	204	208	210
Summary:																	
Average	167.1	167.4	163.7	165.4	161.5	162.3	167.5	165.5	163.7	163.8	161.6	166.2	165.9	166.5	166.9	166.5	165.8
Std Dev	19.8	19.2	17.6	17.7	12.9	14.5	16.9	17.7	17.9	18.7	15.1	19.3	19.1	19.9	19.6	20.1	22.6
Max	207	208	208	206	182	183	205	206	204	204	182	204	204	205	204	208	210
Min	139	139	141	141	140	139	145	139	139	136	137	136	136	141	141	137	138

Units: Pounds

Table 6e-4  
Body Weight

Blank = Not Obtained

Subj \ Day	72	180
01	150	152
02		
03	152	147
04		
05		
06	174	172
07		
08		
09		
10		
11		
12	183	192
13	137	134
14		
15	155	
16		
17		
18		
19	178	
20		
21	204	
Summary:		
Average	166.6	159.4
Std Dev	21.9	22.8
Max	204	192
Min	137	134



Figure 9: SD & Range Charts for Body Weight, Lb

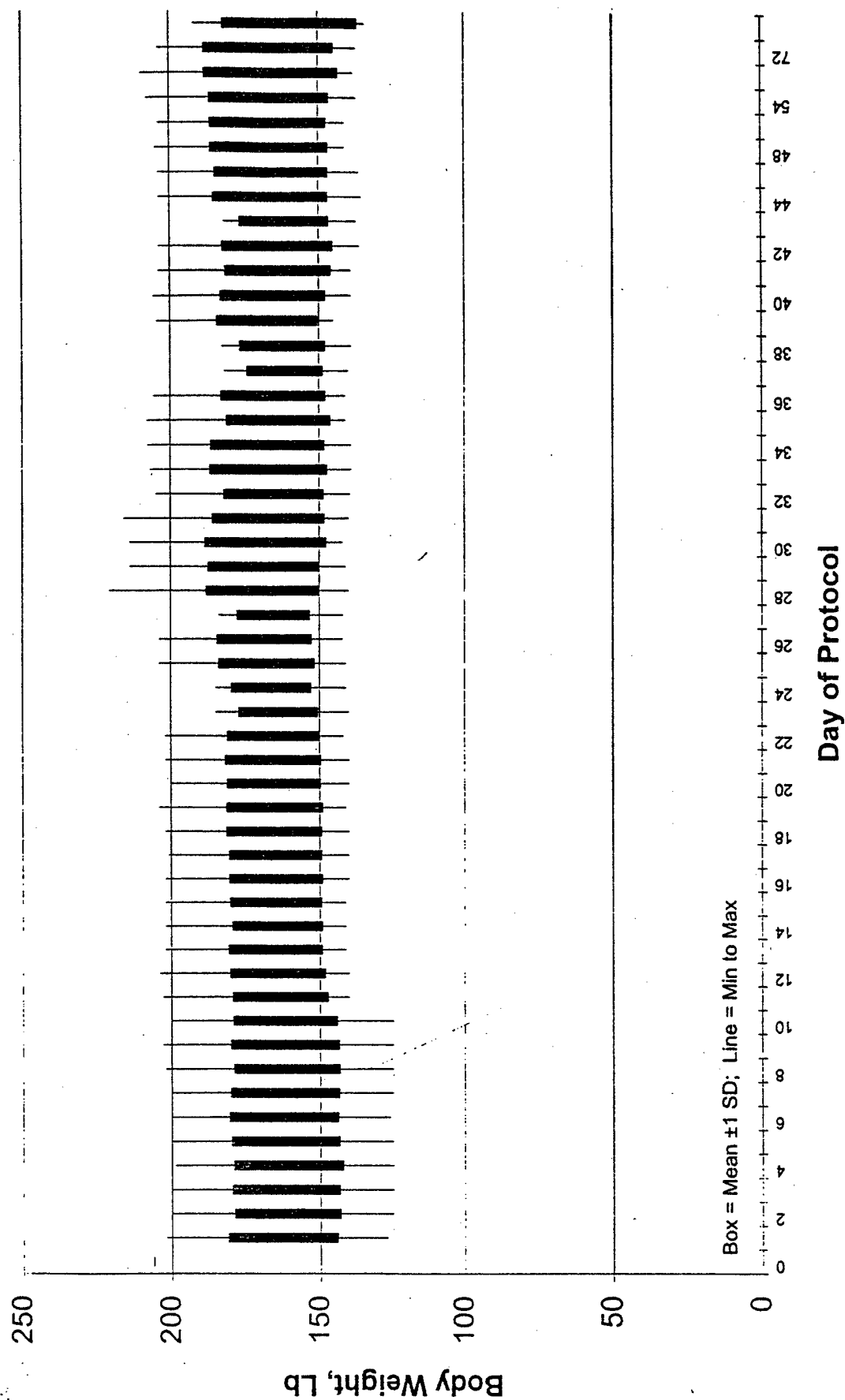


Figure 10: Body Weight, Lb

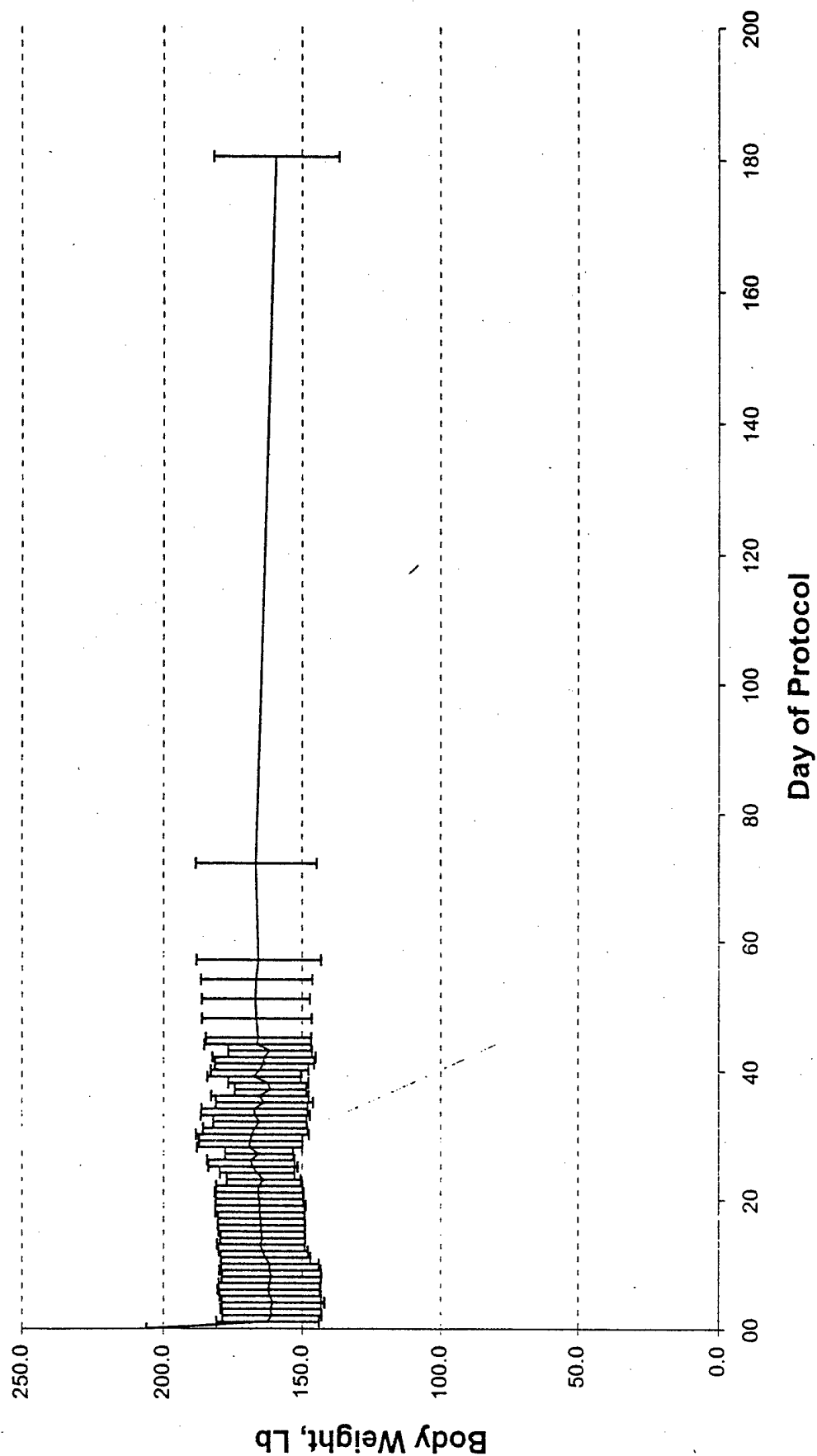


Table 7  
Beta-HCG

Subject	SCR	DAY 0	DAY 28	DAY 54	DAY 84	DAY 112	DAY 140	DAY 168
03	-	-	-	-	-	-		
10	-	-	-	-				
11	-	-						

Blank = Not Obtained

Blank = Not Obtained

Table 8a  
WBC

Thousands/cu mm

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
1	8.1	8.5	6.4	6.2	7.0	7.0	5.1	5.6	5.1	7.4	5.7	6.8	6.0
2	4.5	5.0	3.3	4.6	4.9	5.5	5.7	5.2	3.2				
3	4.5	5.2	5.2	4.1	5.7	4.5	3.5	3.5	3.4	4.0	3.7	5.9	3.0
4	7.5	7.2	6.2	6.8	6.0	7.1	7.0	6.3	6.6	6.4			
5	4.3	3.7	3.2	3.0	3.1	3.5	3.8	3.4	3.1				
6	4.3	4.1	4.0	4.9	4.0	4.2	4.4	4.4	3.9	4.0	3.7	6.4	5.8
7	5.3	5.0	3.9	4.3	4.5	5.7	6.0	4.5		5.0	6.1		
8	3.7	3.6	5.0	5.4	4.3								
9	5.5	6.4	6.6	8.0	7.2	6.7	6.2	5.7	6.8	7.0	5.8		
10	5.3	4.4	4.7	4.5	4.8	4.5	5.2	5.2	4.6	4.4	5.0		
11	8.8	5.6	4.1	4.5	5.4	6.0	7.9	6.3		6.3			
12	6.1	4.5	3.8	4.1	4.1	4.0	4.2	3.7	4.3	3.9	4.3		
13	5.6	6.0	5.0	5.1	5.8	5.5	5.3	4.0	4.6	3.7	6.0		
14	11.7	8.1	7.7	7.7	9.3	6.7	7.0	8.2					
15	6.4	6.0	6.1	6.1	5.4	5.4	5.0	6.4	6.9	6.1	5.8		8.7
16	5.7	6.5	5.6	5.8	5.3	5.6	5.7	5.9	6.0	5.5			
17	6.7	8.4	6.0										
18	4.5	4.6	4.3	5.1	5.7	6.5	6.0	5.0	4.9	3.8	4.6		
19	5.6	7.3	5.7	10.8	8.8	10.8	7.0	6.2	5.2	6.4	5.6		
20	4.7	5.1	3.6	4.4	5.1	4.8	5.2	5.8	3.6	3.3	6.1		
21	6.7	6.9	6.3	6.6	6.6	7.6	6.2	5.4	5.4	5.4	5.4	5.2	
Summary:	WBC, Thousands/cu mm												
Average	6.0	5.8	5.1	5.6	5.7	5.9	5.6	5.3	4.9	5.2	5.2	6.1	5.9
Std Dev	1.9	1.5	1.2	1.8	1.5	1.7	1.2	1.2	1.3	1.3	0.9	0.7	2.3
Max	11.7	8.5	7.7	10.8	9.3	10.8	7.9	8.2	6.9	7.4	6.1	6.8	8.7
Min	3.7	3.6	3.2	3.0	3.1	3.5	3.5	3.4	3.1	3.3	3.7	5.2	3.0

Figure 11: SD &amp; Range Charts for WBC, Thousands/cu mm

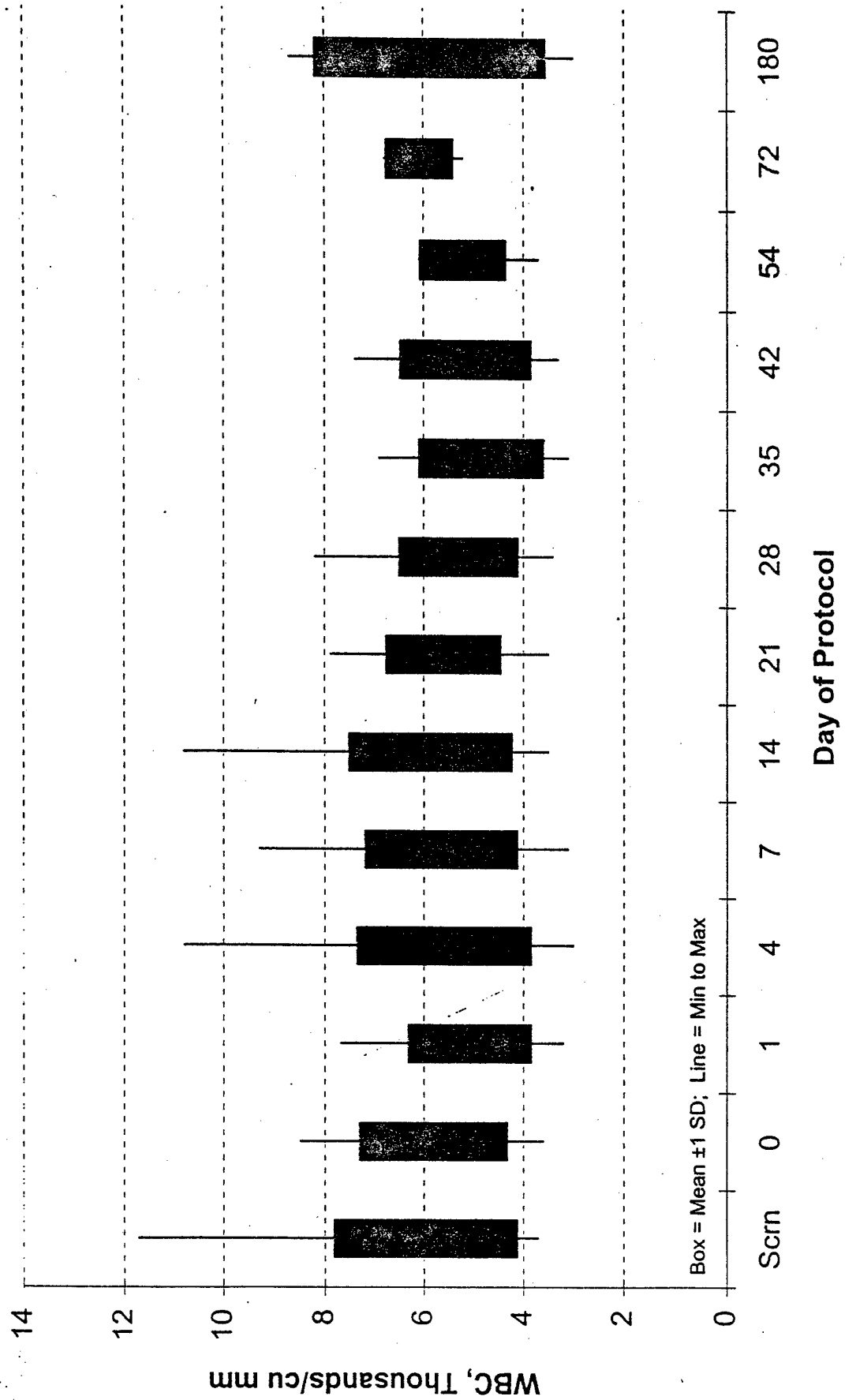
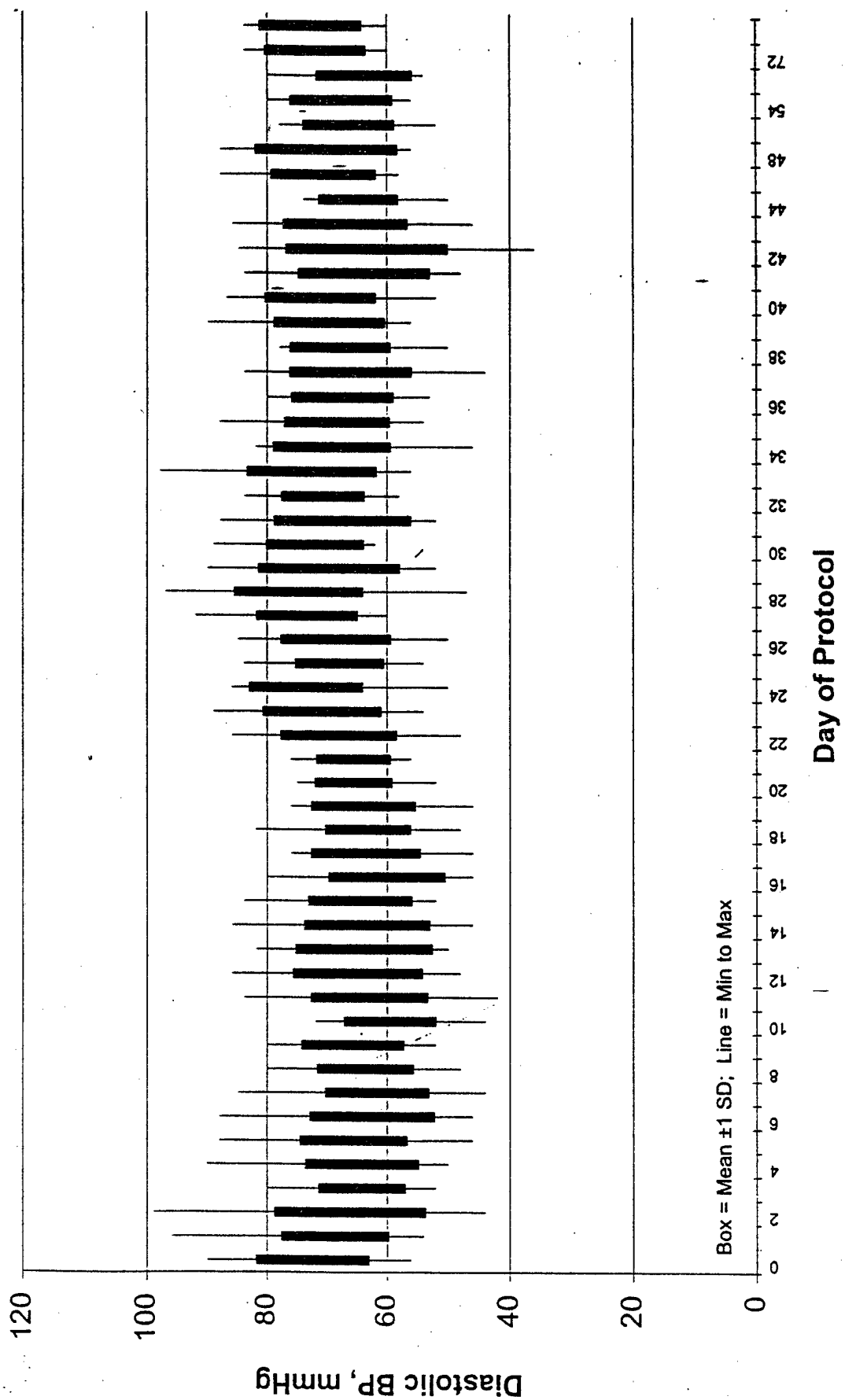


Figure 3: SD &amp; Range Charts for Diastolic BP, mmHg



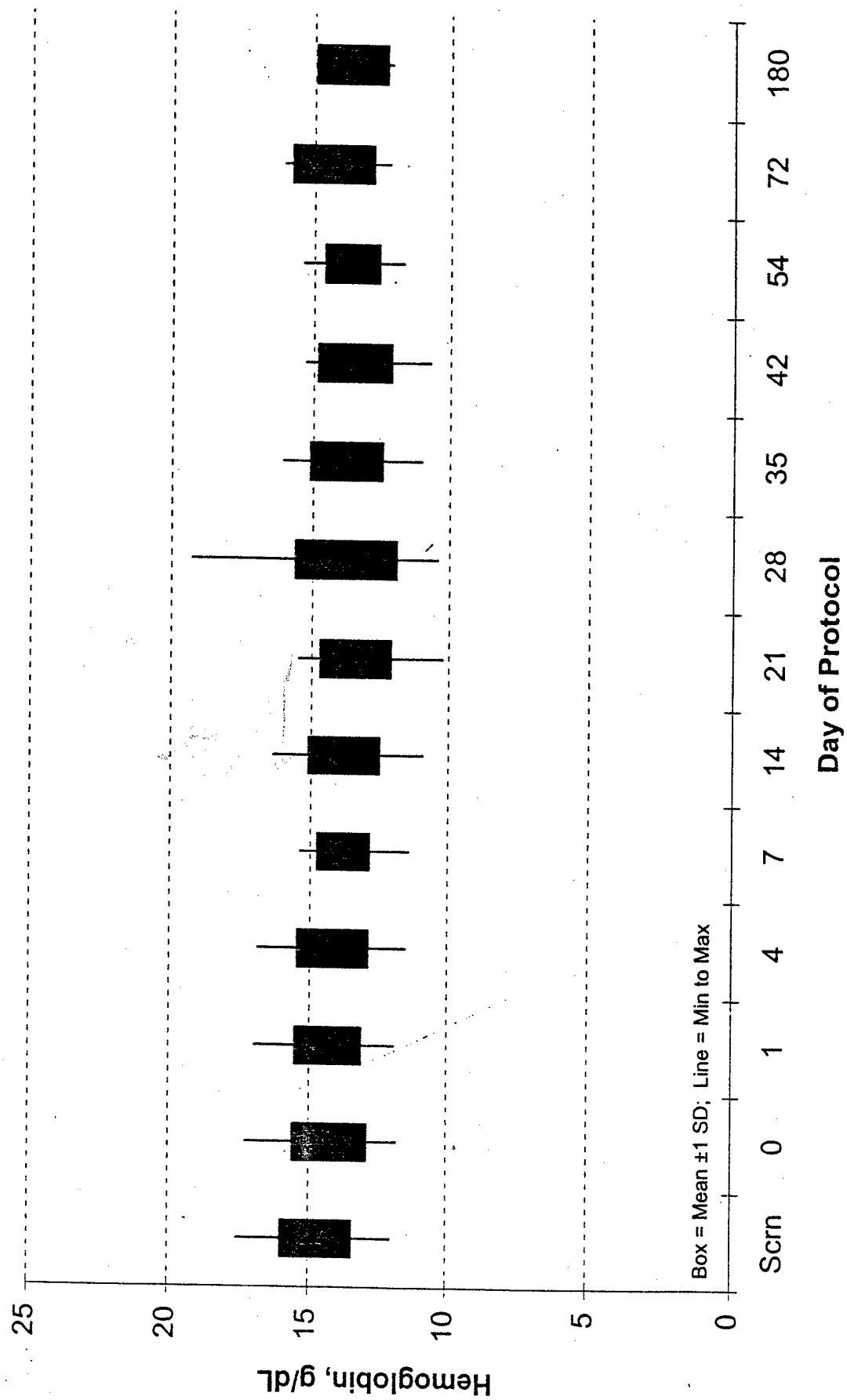
Units: g/dL

Table 8b  
Hemoglobin

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	15.8	17.3	17	14.8	14.9	14.2	15.5	13.2	13.9	13.9	14	14.7	14.3
02	15.3	16.3	14.1	15.4	15.1	16.4	15	15	14.9	14.5			
03	14.1	13.3	15.2	12.9	13.2	14.5	12.5	13.3	11.6	12.5	12.3	12.2	12.1
04	14.9	14.8	15.4	14.8	14.2	14.1	13.6	13.9	13.6				
05	14.8	14	13.7	13.5	13.1	13.2	13.6	14.1					
06	14.2	14.3	14.2	13.8	13.5	13.8	13.1	13.5	14	13.6	13.2	13.4	14.5
07	14.2	12.7	12.4	13	13.3	12.8	12.8	12.2		12	12.7		
08	13.9	13.7	13.7	13.5	13.2								
09	14.2	14.3	14.2	14.8	13.8	13.7	12.9	13.8	12	13.9	13.5		
10	12	11.8	11.9	11.5	11.4	11.4	10.2	10.8	11	11.4	11.7		
11	12	11.9	12	11.7	12.1	10.9	11.3	10.4		10.7			
12	15.6	13	14.2	13.8	14	13	13.2	13.8	14.1	13.9	13.8		
13	14.9	14.4	14.7	14	13.6	13.4	13.8	13.6	13.9	14.7	13.4		
14	15.4	14	14.2	15.1	13.8	15.3	15	14.4	14.8				
15	17.6	15.9	15.4	15.8	14.4	14.9	13	15.8	16.1	14.8	14.5		
16	14.7	13.8	13.9	14.4	13.8	12.9	13.2	13.3	13.6	12.3			
17	16.2	16.1	16										
18	13	13.4	13.6	13.5	13.4	13.2	12.6	12.4	12.7	12.8	13.1		
19	15.1	14.5	15	15.5	15.4	15.3	14.8	14.7	14.8	14.7	14.5		
20	15.9	14.4	15	16.9	14.9	14.6	15.1	19.3	15	14.9	15.4	16.1	
21	15.2	15.1	14.8	14.5	14.9	14.6	13.5	14.2	14.5	15.3	14.7	15.1	
Summary:	Hemoglobin, g/dL												
Average	14.7	14.2	14.3	14.2	13.8	13.8	13.4	13.8	13.8	13.5	13.6	14.3	13.6
Std Dev	1.3	1.4	1.2	1.3	1.0	1.3	1.3	1.9	1.4	1.4	1.0	1.5	1.3
Max	18	17	17	17	15	16	16	19	16	15	15	16	15
Min	12	12	12	12	11	11	10	10	11	11	12	12	12

Blank = Not Obtained

Figure 12: SD &amp; Range Charts for Hemoglobin, g/dL





Units: mmHg

Table 3  
Vital Signs: Diastolic BP

Blank = Not Obtained

Subj \ Day	42	43	44	45	48	51	54	57	72	180
01	78	56	64	70	64	72	62	54	66	64
02				58						
03	50	68	58		56	60	56	54	60	60
04										
05				88						
06	70	78	62		86	78	80	70	62	84
07	72	74				64	56	80	64	82
08										66
09	60	58	68	62	62	62	62	68	74	76
10	66	76	74	74		60	72			
11	48	65	68	80						
12	85	86	64	73	78	77	72	72	78	74
13	52	60	60	63	60	70	60	56	73	64
14										
15	55	68	50	66	60	60	66	60	81	78
16	66	66	64							80
17										
18	78	79		62	86	52	80	68	82	
19	74	46	72	80	88	74	78	65	68	
20	36	64	74	76	68	66	72	58		
21	62	60	64	66	64	68	63	61	84	
Summary:										
average	63.5	66.9	64.8	70.6	70.2	66.4	67.6	63.8	72.0	72.8
stdev	13.4	10.4	6.7	8.8	12.0	7.7	8.6	8.1	8.5	8.6
max	85	86	74	88	88	78	80	80	84	84
min	36	46	50	58	56	52	56	54	60	60

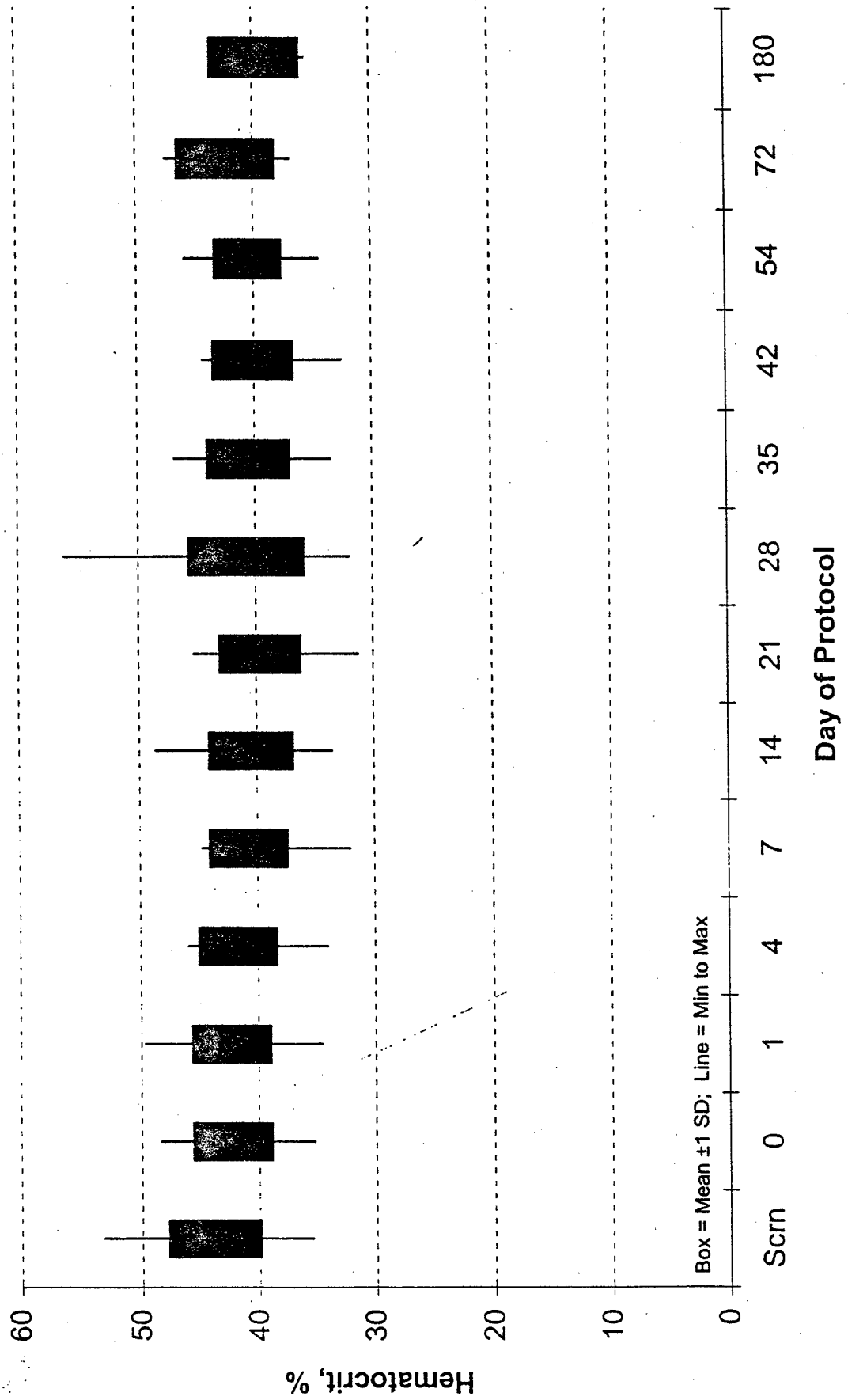
Units: %

Table 8c

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
1	46.5	48.0	49.7	43.5	43.0	41.0	45.4	38.8	40.3	40.9	41.8	44.5	43.0
2	45.3	46.0	41.9	45.2	44.3	48.7	44.4	43.3	43.4	43.3			
3	41.8	40.1	44.6	37.6	39.7	42.2	37.6	38.7	34.5	37.0	36.8	36.8	35.5
4	47.4	42.9	45.2	43.2	42.1	41.0	39.8	41.8	40.5				
5	41.6	42.2	41.2	40.6	39.5	39.0	41.4	43.2					
6	42.0	41.2	41.7	40.5	39.4	39.9	37.8	38.9	39.7	40.0	39.7	39.3	41.0
7	43.0	38.3	37.9	39.3	36.8	37.0	38.7	38.9		36.8	39.1		
8	42.9	41.8	40.8	41.3	39.5								
9	42.9	42.8	41.7	44.5	36.4	39.9	39.3	42.5	36.2	42.2	40.3		
10	35.4	35.3	35.8	34.3	32.0	33.5	31.2	33.4	33.5	34.6	34.4		
11	36.5	35.2	34.5	34.0	36.2	33.6	35.4	31.9		32.5			
12	47.9	40.0	43.4	43.0	42.9	39.4	40.0	40.0	40.5	40.6	40.4		
13	44.9	42.5	43.2	40.9	40.0	37.8	39.4	38.6	40.6	42.5	40.2		
14	44.5	41.7	41.4	43.9	44.3	44.1	44.1	42.4	44.2				
15	53.3	46.8	43.9	46.0	43.9	42.2	37.0	45.0	47.0	43.5	41.8		
16	43.5	42.6	43.0	42.8	42.3	38.4	39.0	39.7	41.3	37.6			
17	48.3	48.4	47.4										
18	38.9	40.2	40.4	40.8	40.5	40.8	37.0	37.4	38.4	39.6	39.6		
19	45.5	44.1	44.0	45.3	44.8	45.0	44.1	43.0	43.9	42.9	42.7		
20	45.5	42.4	43.6	45.5	44.3	43.3	43.5	56.3	44.0	43.5	46.0	47.6	
21	42.9	43.8	42.8	41.9	43.3	42.8	38.9	41.4	41.0	44.5	43.8	43.3	
Summary:	Hematocrit, %												
Average	43.8	42.2	42.3	41.7	40.8	40.5	39.7	40.8	40.6	40.1	40.5	42.3	39.8
Std Dev	4.0	3.5	3.4	3.4	3.4	3.7	3.5	5.0	3.6	3.5	2.9	4.3	3.9
Max	53.3	48.4	49.7	46.0	44.8	48.7	45.4	56.3	47.0	44.5	46.0	47.6	43.0
Min	35.4	35.2	34.5	34.0	32.0	33.5	31.2	31.9	33.5	32.5	34.4	36.8	35.5

Figure 13: SD & Range Charts for Hematocrit, %



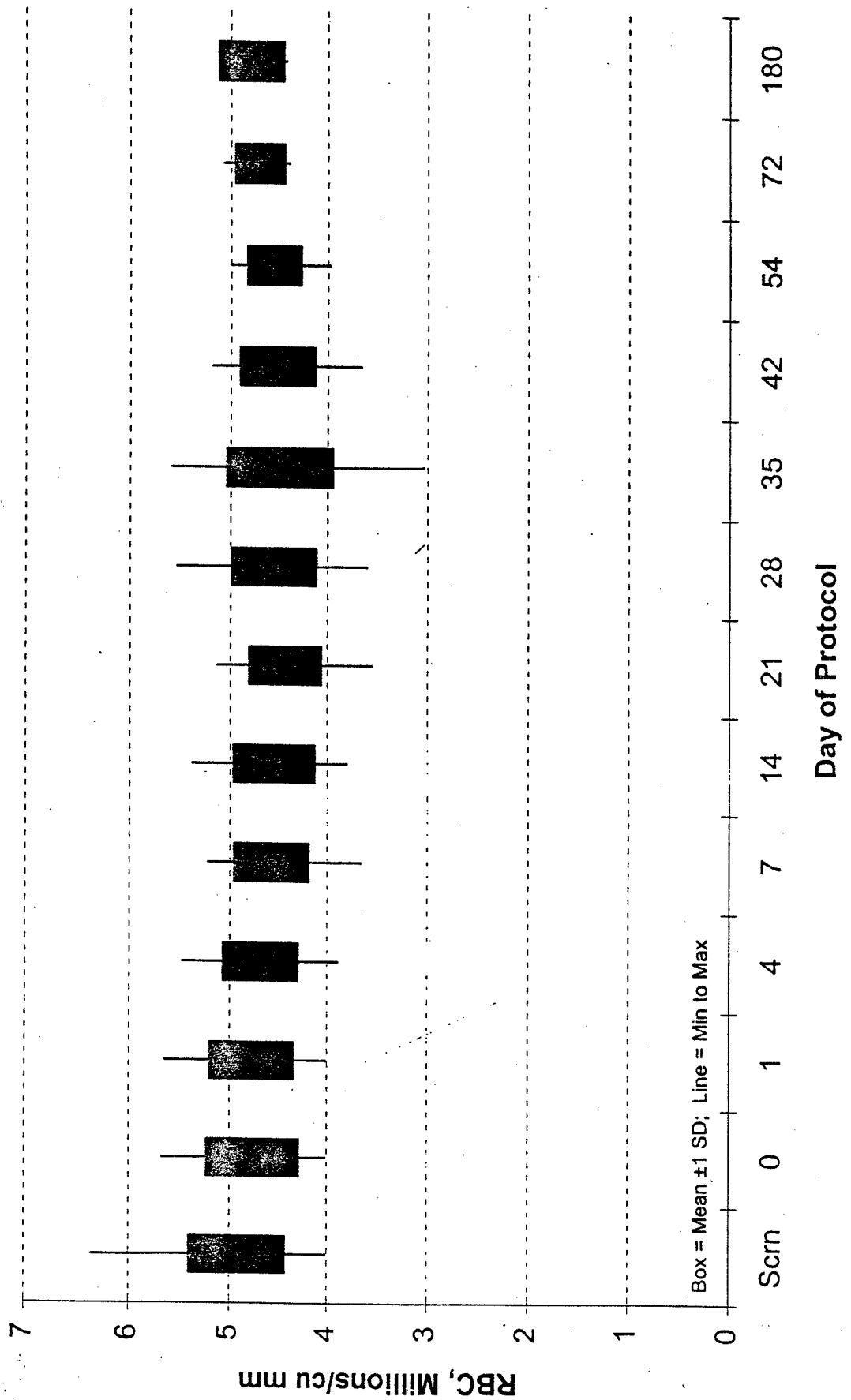
Units: Million / cu mm

Table 8d  
RBC

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
1	5.29	5.49	5.66	4.93	4.94	4.71	5.14	4.42	4.60	4.63	4.74	5.08	5.09
2	4.99	5.18	4.67	5.01	4.92	5.39	4.92	4.90	4.94	4.87			
3	4.76	4.57	5.12	4.31	4.49	4.90	4.33	4.50	3.03	4.37	4.28	4.39	4.42
4	5.30	4.76	4.99	4.84	4.63	4.58	4.43	4.61	4.50				
5	4.78	4.85	4.72	4.67	4.59	4.56	4.74	4.98					
6	4.86	4.80	4.81	4.69	4.85	4.65	4.35	4.48	4.58	4.64	4.59	4.54	4.86
7	4.77	4.32	4.18	4.36	3.98	4.15	4.16	4.31		4.21	4.47		
8	5.01	4.94	4.83	4.85	4.71								
9	4.88	4.90	4.81	5.03	4.15	4.57	4.46	4.84	4.15	4.79	4.55		
10	4.01	4.01	4.07	3.91	3.66	3.82	3.55	3.82	3.85	3.99	3.97		
11	4.18	4.01	4.01	3.89	4.15	3.80	3.98	3.60		3.66			
12	4.99	4.18	4.54	4.50	4.47	4.15	4.16	4.22	4.34	4.28	4.27		
13	5.01	4.76	4.82	4.52	4.42	4.25	4.39	4.30	4.48	4.71	4.42		
14	4.71	4.51	4.51	4.75	4.68	4.72	4.72	4.56	4.75				
15	6.36	5.68	5.37	5.49	5.22	5.08	4.51	5.10	5.60	5.19	5.01		
16	4.91	4.75	4.82	4.79	4.65	4.32	4.46	4.44	4.63	4.25			
17	5.61	5.65	5.54										
18	4.49	4.70	4.73	4.73	4.70	4.73	4.43	4.40	4.45	4.51	4.64		
19	5.27	5.01	5.09	5.28	5.23	5.18	5.12	4.99	5.08	4.97	4.97		
20	4.47	4.19	4.31	4.62	4.34	4.22	4.27	5.54	4.35	4.30	4.57	4.77	
21	4.76	4.79	4.72	4.61	4.76	4.66	4.20	4.49	4.57	4.90	4.74	4.74	
Summary:	RBC, Millions/cu mm												
Average	4.92	4.76	4.78	4.69	4.58	4.55	4.44	4.55	4.49	4.52	4.56	4.70	4.79
Std Dev	0.49	0.48	0.44	0.39	0.39	0.43	0.38	0.45	0.55	0.40	0.29	0.26	0.34
Max	6.36	5.68	5.66	5.49	5.23	5.39	5.14	5.54	5.60	5.19	5.01	5.08	5.09
Min	4.01	4.01	4.01	3.89	3.66	3.80	3.55	3.60	3.03	3.66	3.97	4.39	4.42

Figure 14: SD & Range Charts for RBC, Millions/cu mm



Blank = Not Obtained

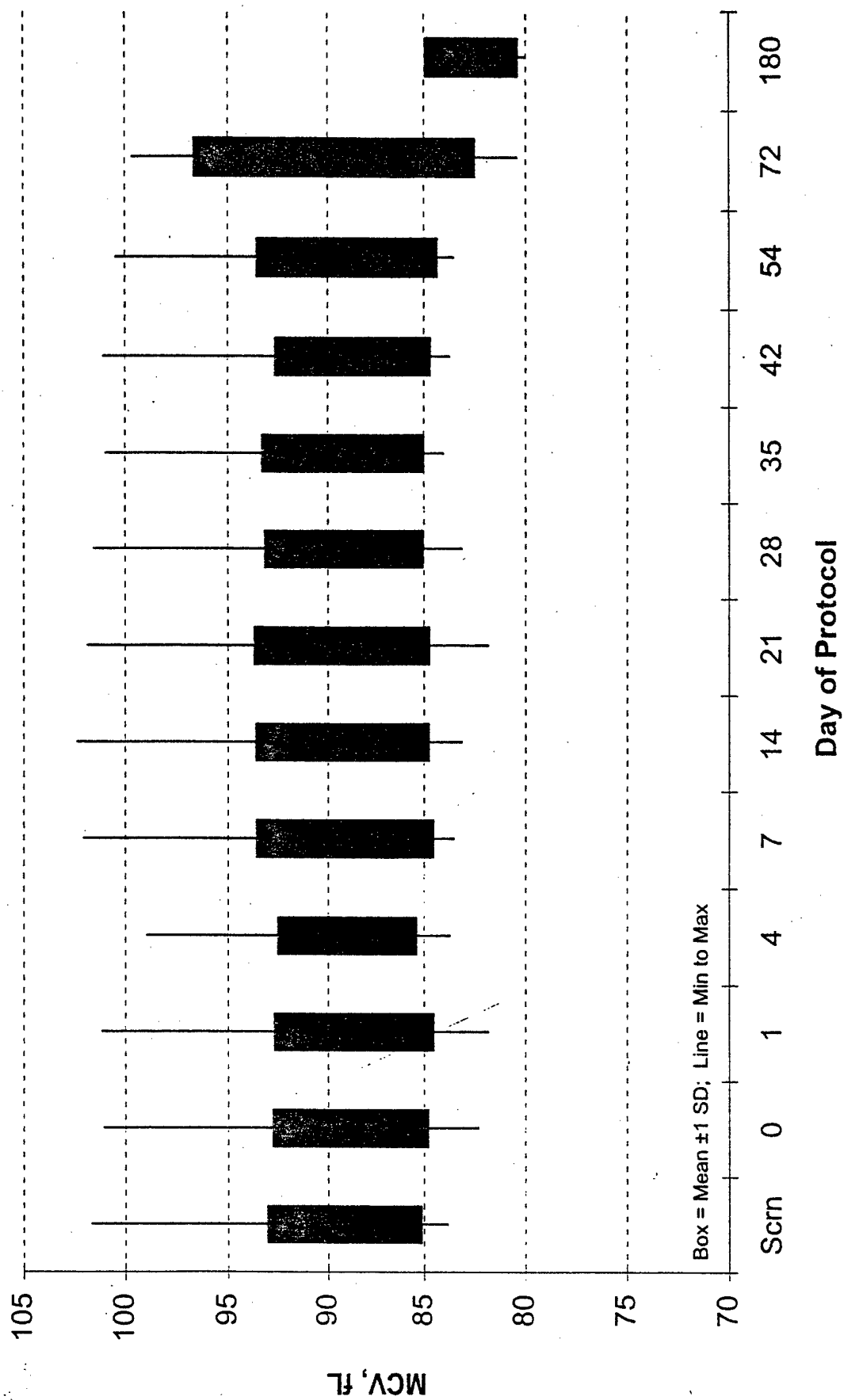
Table 8a

Units: Femtoliters

MCV

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	88.0	87.0	87.8	88.2	87.0	86.9	88.2	87.5	87.6	88.2	88.1	87.5	84.0
02	90.7	89.0	89.7	90.1	90.0	90.3	90.2	88.3	87.8	88.9			
03	87.8	87.8	86.9	87.2	88.4	86.0	86.9	85.8	85.6	84.8	85.9	83.8	80.0
04	89.3	90.0	90.6	89.5	90.9	89.0	89.9	90.7	90.0				
05	87.0	86.8	87.2	86.8	86.0	85.0	87.3	86.6					
06	86.4	85.8	86.7	86.0	86.0	85.7	87.0	86.8	86.7	86.3	86.6	80.4	84.0
07	90.0	90.3	90.7	90.1	90.0	88.6	89.0	89.7		87.4	87.4		
08	85.6	84.6	84.5	85.1	84.0								
09	87.9	87.2	86.7	88.3	83.5	87.1	88.2	87.7	87.3	88.0	88.6		
10	88.3	88.0	88.0	87.7	87.6	87.5	87.7	87.4	86.9	86.6	86.5		
11	87.3	87.6	86.0	87.4	87.2	88.5	88.8	88.5		88.8			
12	95.9	95.4	95.6	95.6	96.0	95.8	96.2	94.2	94.7	93.0	94.7	94.6	
13	89.5	89.3	89.6	90.3	90.3	88.9	89.6	89.9	90.6	90.2	91.0		
14	94.0	92.4	91.2	92.4	94.7	93.2	93.4	92.8	92.8				
15	83.8	82.3	81.8	83.7	83.9	83.1	81.8	83.1	84.0	83.7	83.5		
16	89.0	89.7	89.3	89.3	91.0	89.0	87.0	89.4	89.1	88.4			
17	85.9	85.6	85.6										
18	86.6	85.5	85.2	86.1	86.1		83.0	85.1	86.1	86.5	85.4		
19	86.3	87.9	86.0	85.8	85.6	86.7	86.2	85.9	86.4	86.2	85.8		
20	101.7	101.1	101.2	99.0	102.1	102.4	101.9	101.6	101.0	101.1	100.5	99.7	
21	90.0	91.4	90.7	90.8	90.8	91.7	92.7	92.1	90.0	90.7	92.4	91.4	
Summary:	MCV, fL												
Average	89.1	88.8	88.6	89.0	89.1	89.2	89.2	89.1	89.2	88.7	89.0	89.6	82.7
Std Dev	04.0	04.0	04.1	03.6	04.6	04.5	04.5	04.1	04.2	04.0	04.6	07.1	02.3
Max	101.7	101.1	101.2	99.0	102.1	102.4	101.9	101.6	101.0	101.1	100.5	99.7	84.0
Min	83.8	82.3	81.8	83.7	83.5	83.1	81.8	83.1	84.0	83.7	83.5	80.4	80.0

Figure 15: SD & Range Charts for MCV, fL



g/dL

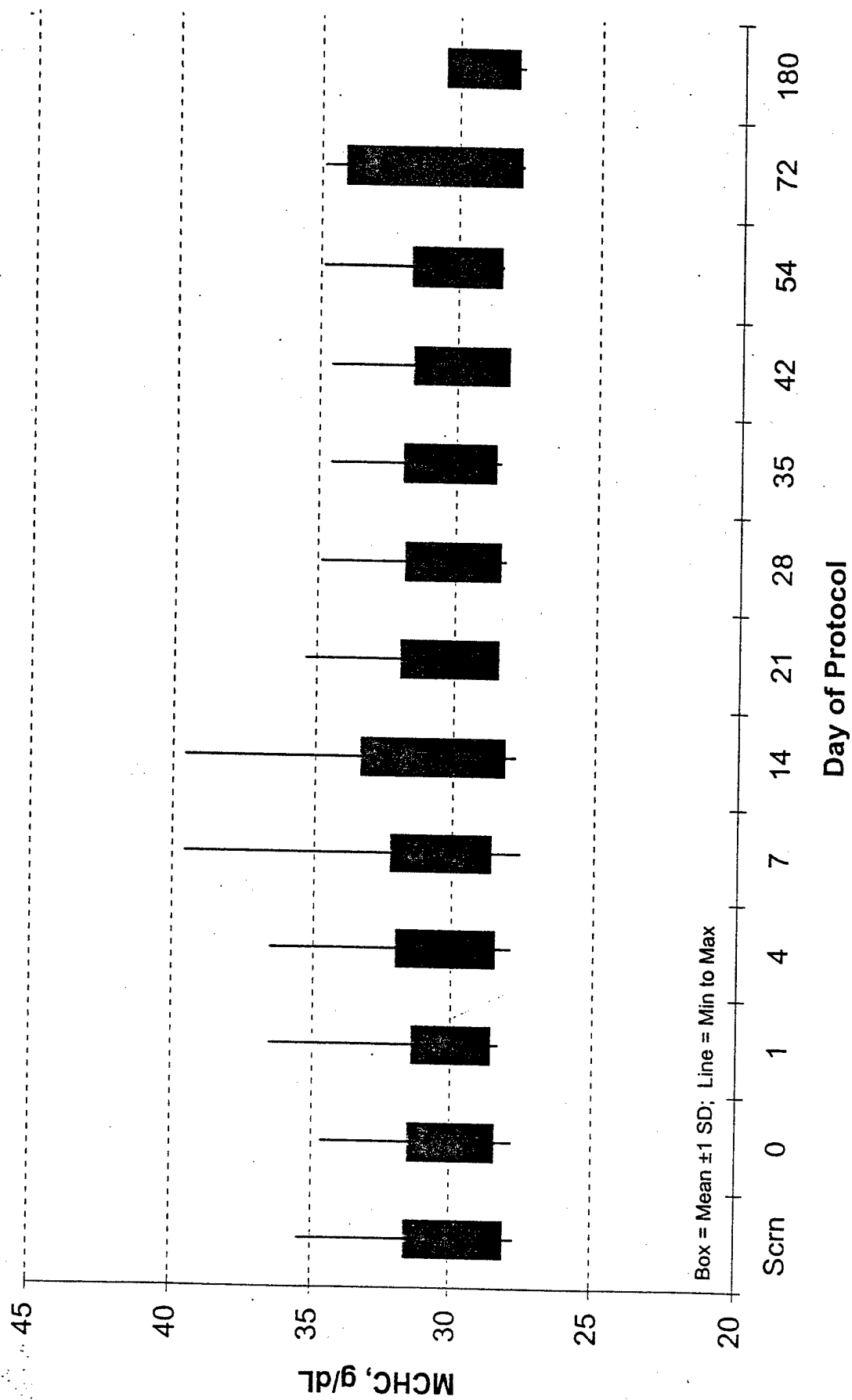
Table 8f  
MCHC

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	29.9	31.5	30.0	30.1	30.2	30.1	30.1	29.8	30.3	30.1	29.6	29.0	30.1
02	30.6	31.5	30.1	30.8	30.8	30.3	30.4	30.6	30.1	29.8			
03	29.6	29.1	29.6	29.9	29.4	29.6	28.9	29.5	28.8	28.7	28.9	27.7	27.7
04	28.2	31.0	31.0	30.6	30.6	30.8	30.7	30.2	30.2				
05	28.9	28.9	29.0	28.9	28.5	28.9	28.6	28.3					
06	29.3	29.7	29.5	29.4	29.4	29.7	30.1	30.0	30.6	29.4	28.9	29.4	29.8
07	29.8	30.1	29.7	29.8	33.4	30.8	30.8	28.3		28.4	28.4		
08	27.9	27.8	28.3	27.9	28.0								
09	29.2	29.3	29.6	29.3	33.2	29.9	28.8	28.6	28.8	29.0	29.8		
10	29.8	29.5	29.2	29.4	31.3	29.9	28.7	28.2	28.6	28.5	29.5		
11	28.8	29.6	29.9	30.0	29.1	28.6	28.5	29.0		29.3			
12	31.2	31.2	31.3	30.8	31.3	31.5	31.8	32.7	32.5	32.5	32.3		
13	29.8	30.2	30.5	31.0	30.8	39.6	31.5	31.5	31.1	31.2	30.4		
14	32.7	31.1	31.5	31.8	31.7	32.4	31.8	31.5	31.2				
15	27.7	28.0	28.7	28.9	27.6	29.4	28.8	29.9	28.8	28.5	29.0		
16	29.9	29.0	28.9	30.1	29.6	29.9	29.6	29.9	29.3	29.0			
17	28.9	28.4	28.9										
18	28.9	28.5	28.6	28.5	28.5	27.8	28.4	28.3	28.4	28.3			
19	28.6	29.0	29.5	29.5	29.4	29.5	28.9	29.4	29.1	29.6	29.1		
20	35.5	34.4	34.7	36.6	34.4	34.7	35.4	34.9	34.6	34.6	33.9	33.8	
21	31.9	31.6	31.4	31.5	31.4	31.3	32.0	31.6	31.7	31.2	31.1	34.9	
Summary:	MCHC, g/dL												
Average	29.9	30.0	30.0	30.2	30.4	30.8	30.2	30.1	30.3	29.9	30.1	31.0	29.2
Std Dev	01.8	01.6	01.4	01.8	01.8	02.6	01.8	01.7	01.7	01.7	01.6	03.2	01.3
Max	35.5	34.7	36.6	36.6	39.6	39.6	35.4	34.9	34.6	34.6	34.9	34.9	30.1
Min	27.7	27.8	28.3	27.9	27.6	27.8	28.4	28.2	28.4	28.3	28.4	27.7	27.7



Figure 16: SD &amp; Range Charts for MCHC, g/dL



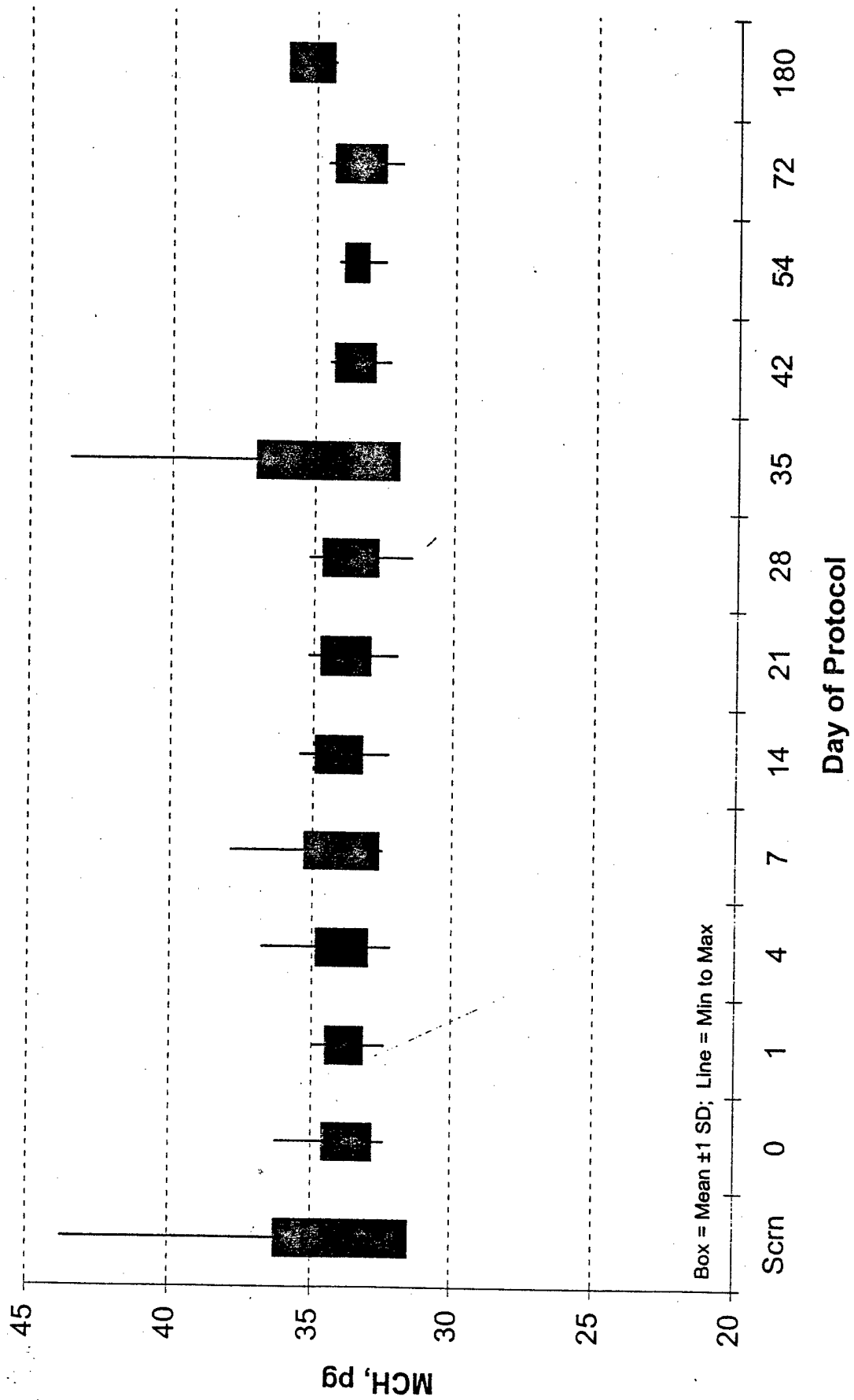
Blank = Not Obtained

Table 8g  
MCH

Units: Picograms

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	34.1	36.3	34.2	34.1	34.7	34.6	34.1	34.0	43.6	34.1	33.6	33.2	35.9
02	33.7	35.3	33.6	34.1	34.2	33.6	33.7	34.7	34.3	33.5			
03	33.7	33.2	34.1	34.3	33.2	34.4	33.3	34.3	33.6	33.8	33.6	33.1	34.3
04	31.5	34.4	34.2	34.1	33.6	34.5	34.2	33.3	33.6				
05	33.2	33.3	33.3	33.2	33.3	33.9	32.8	32.7					
06	33.8	34.6	34.0	34.3	34.2	34.7	34.8	34.5	35.3	34.0	33.3	34.0	35.4
07	33.3	33.3	32.7	33.1	37.1	34.8	34.8	31.5		32.5	32.5		
08	32.5	32.9	33.4	32.8	33.3								
09	33.2	33.5	34.1	33.2	37.9	34.4	32.7	32.6	33.0	33.0	33.6		
10	33.7	33.5	33.2	33.5	33.4	34.1	32.7	32.3	32.9	32.9	34.0		
11	32.9	33.8	34.7	34.3	33.3	32.3	32.0	32.7		33.0			
12	32.8	32.6	32.7	32.2	32.6	33.1	33.1	34.5	35.0	34.3	34.2		
13	33.3	33.8	34.0	34.3	34.1	35.5	35.2	35.1	34.4	34.5	33.4		
14	43.8	33.6	34.5	34.4	33.5	34.7	34.0	33.9	33.6				
15	33.1	33.9	35.0	34.5	32.9	35.3	35.1	35.2	34.3	34.1	34.1	34.6	
16	33.1	32.4	32.4	33.7	32.5	33.6	34.1	33.4	32.8	32.8			
17	33.5	33.2	33.7										
18	33.3	33.2	33.6	33.0	33.1	32.3	34.3	33.2	33.0	32.3	33.1		
19	33.1	32.9	34.4	34.3	34.3	34.0	33.6	34.2	33.7	34.4	33.9		
20	34.9	34.0	34.3	36.8	33.6	33.8	34.7	34.4	34.2	34.2	33.5	33.9	
21	35.4	34.5	34.5	34.6	34.5	34.1	34.5	34.3	35.2	34.4	33.7	31.9	
Summary:	MCH, pg												
Average	33.9	33.7	33.8	33.9	34.0	34.1	33.9	33.7	34.5	33.6	33.6	33.5	35.2
Std Dev	02.4	00.9	00.7	00.9	01.4	00.9	00.9	01.0	02.5	00.7	00.5	00.9	00.8
Max	43.8	36.3	35.0	36.8	37.9	35.5	35.2	35.2	43.6	34.5	34.2	34.6	35.9
Min	31.5	32.4	32.4	32.2	32.5	32.3	32.0	31.5	32.8	32.3	32.5	31.9	34.3

Figure 17: SD & Range Charts for MCH, pg



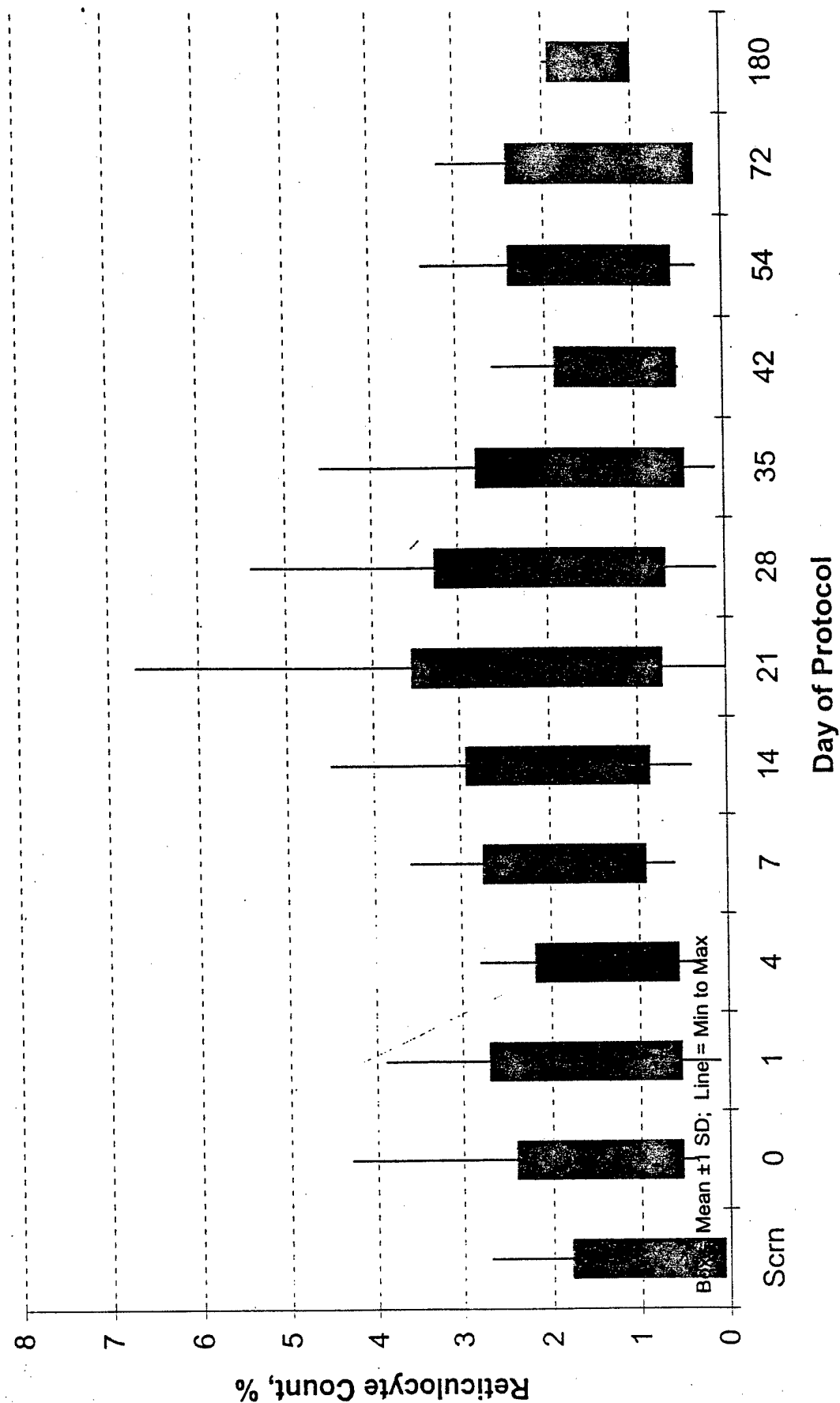
Units: %

Table 8h  
Reticulocyte Count

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01		2.0	0.7	2.5	1.8	1.5	1.5	1.5	2.0	1.5	1.9	1.0	1.1
02		1.5	0.1	1.8	1.9	1.4	2.0	0.4	1.9	0.5			
03		1.0	1.5	0.7	3.5	1.2	2.0	0.1	2.0	1.4	1.6	1.2	1.3
04	0.6	1.2	2.5	2.8	1.9	2.0	3.0	4.4	1.0				
05	1.2	2.3	2.0	2.5	2.4	1.5	1.5	2.8					
06		0.4	1.0	0.5		3.6	1.6	1.5	1.0	1.0	0.8	0.9	2.0
07	1.0	0.5	0.2	1.1	1.0	2.4	3.8	1.3		1.4	0.8		
08	0.6	1.0	1.6	0.4	1.5								
09	0.1	1.3	1.2	1.2	1.0	2.0	2.5	1.0	2.4	0.5	0.3		
10		2.0	0.1	0.3	1.0	1.7	2.0	1.1	0.1	0.6	1.2		
11	2.7	4.3	2.1	0.9	3.0	4.5	6.7	5.4		1.0			
12		2.5	2.8	2.0	1.3	1.1	0.0	2.0	4.6	1.2			
13			3.3		1.4	1.8	1.5	1.8	2.0	1.1	1.3		
14			3.9	2.3	2.4	1.7	2.4	2.2	0.3				
15			2.7	2.0	3.6	1.7	1.6	2.6	1.5	2.6	2.8		
16			2.1	1.0	0.8	0.8	1.3	2.7	0.9	0.5			
17		1.0	1.0										
18		1.2	1.3	0.6	0.6	0.8	0.9	1.5	1.5	2.4	0.9		
19		0.9	0.3	0.7	1.0	0.4	1.8	1.0	0.3				
20		0.9			1.8	2.5	3.5	3.0	1.0	2.0	1.4	3.2	
21	0.3	1.0	2.0	1.4	3.0	3.5	1.0	1.2	3.4	0.5	3.4	0.5	
Summary:	Reticulocyte Count, %												
Average	0.9	1.5	1.6	1.4	1.8	1.9	2.1	2.0	1.6	1.2	1.5	1.4	1.5
Std Dev	0.9	0.9	1.1	0.8	0.9	1.0	1.4	1.3	1.2	0.7	0.9	1.1	0.5
Max	2.7	4.3	3.9	2.8	3.6	4.5	6.7	5.4	4.6	2.6	3.4	3.2	2.0
Min	0.1	0.4	0.1	0.3	0.6	0.4	0.0	0.1	0.1	0.5	0.3	0.5	1.1

Figure 18: SD & Range Charts for Reticulocyte Count, %



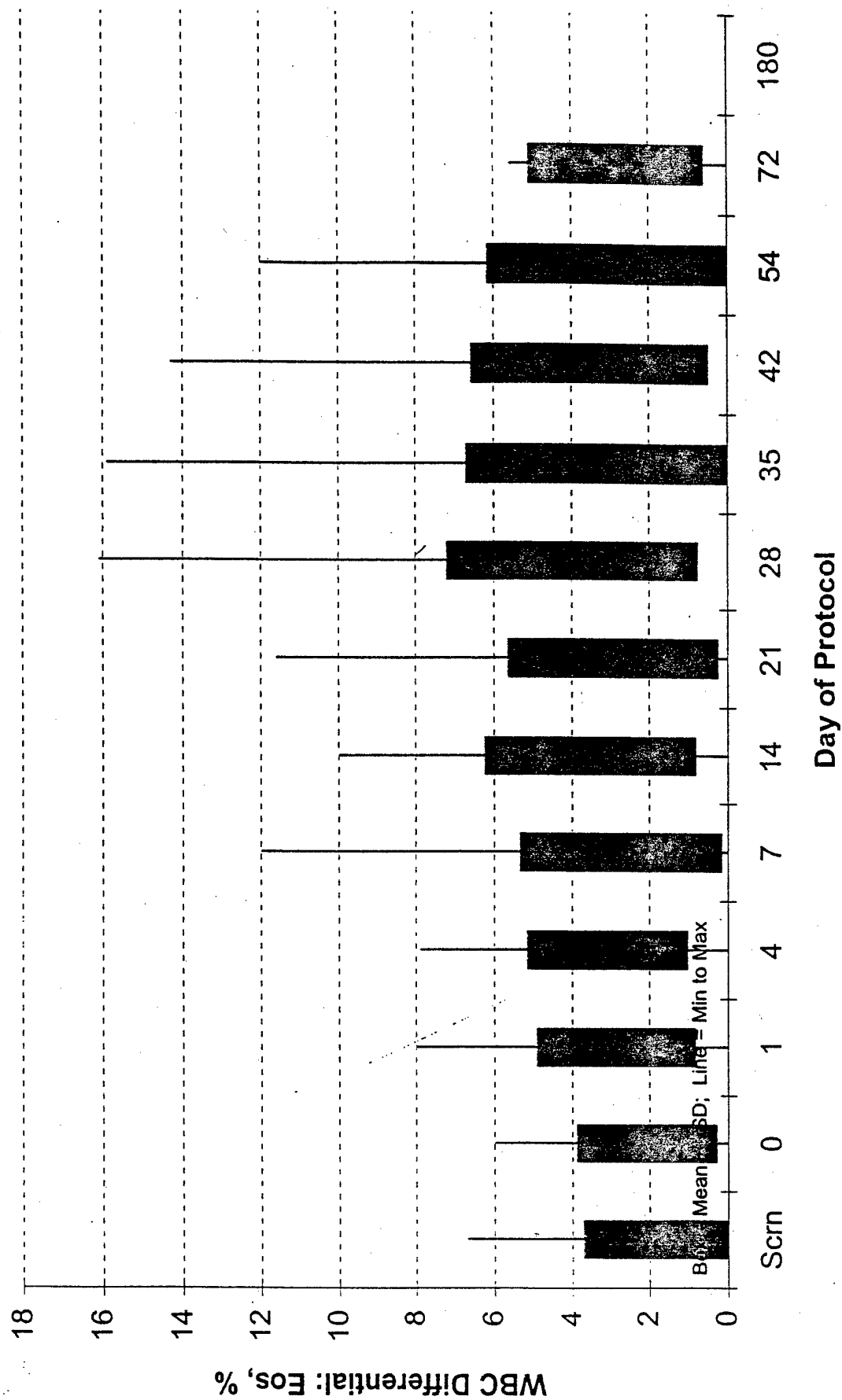
Units: %

Table 81  
WBC Differential: Eosinophils

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	0.0	0.0	5.1	5.1	4.6	5.4	6.2	5.8	5.6	3.3	3.9	5.6	0.0
02	0.0	0.0	3.0	4.8	4.9	5.1	5.5	6.2	0.3	1.9			
03	1.2	1.3	1.2	2.1	1.3	2.2	2.3	2.5	1.7	1.4	3.5	0.0	0.0
04		1.1	1.3	1.0	1.7	0.0	0.9	0.8	0.0				
05	4.7	6.0	5.7	4.0	0.0	0.0	3.8	3.4					
06	0.0	0.7	1.9	0.0	1.9	2.3	1.9	2.7	2.1	2.2	1.5	2.0	0.0
07	0.0	2.8	3.6	5.6	3.8	6.0	0.0	3.9		3.5	0.0		
08	4.0	5.4	5.9	6.0	0.0								
09	1.2	1.0	2.5	2.3	1.3	2.0	1.7	1.5	0.8	1.7	1.0		
10	2.0	2.5	2.3	1.2	2.0	1.8	1.8	2.9	1.7	2.1	1.8		
11	2.4	0.9	0.0	4.0	0.0	3.3	3.1	3.8		4.7			
12	0.9	0.8	1.6	2.4	2.0	2.2	1.6	1.8	0.0	1.7	1.7		
13	2.5	1.4	4.2	3.7	3.1	3.8	3.5	3.5	4.3	5.1	4.7	4.7	
14	0.0	1.4	2.0	2.0	1.2	1.7	2.0	4.1	2.0				0.0
15	6.7	5.2	8.0	7.9	12.0	9.6	11.6	16.1	15.9	14.3	12.0		
16	0.0	2.2	3.2	3.3	3.2	3.7	0.0	4.9	3.5	3.0			
17													
18	2.8	3.6	1.0	1.0	3.7	3.4	0.0	3.2	3.1	3.1	2.4		
19	2.7	2.8	0.0	3.0	2.6	2.0	3.3	3.4	3.3	2.7	3.0		
20	2.2	0.0	3.0	0.0	2.7	10.0	4.0	2.3	2.0	2.5	1.1	2.0	
21	2.1	2.6	2.3	2.7	3.1	2.6	2.8	3.0	0.0	3.4			
Summary	WBC Differential: Eos, %												
Average	1.9	2.1	2.9	3.1	2.8	3.5	2.9	4.0	2.9	3.5	3.1	2.9	0.0
Std Dev	1.8	1.8	2.1	2.1	2.6	2.7	2.7	3.2	3.8	3.1	3.1	2.3	0.0
Max	6.7	6.0	8.0	7.9	12.0	10.0	11.6	16.1	15.9	14.3	12.0	5.6	0.0
Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.8	0.0	1.4	0.0	0.0	0.0

Figure 19: SD &amp; Range Charts for WBC Differential: Eos, %



Units: %

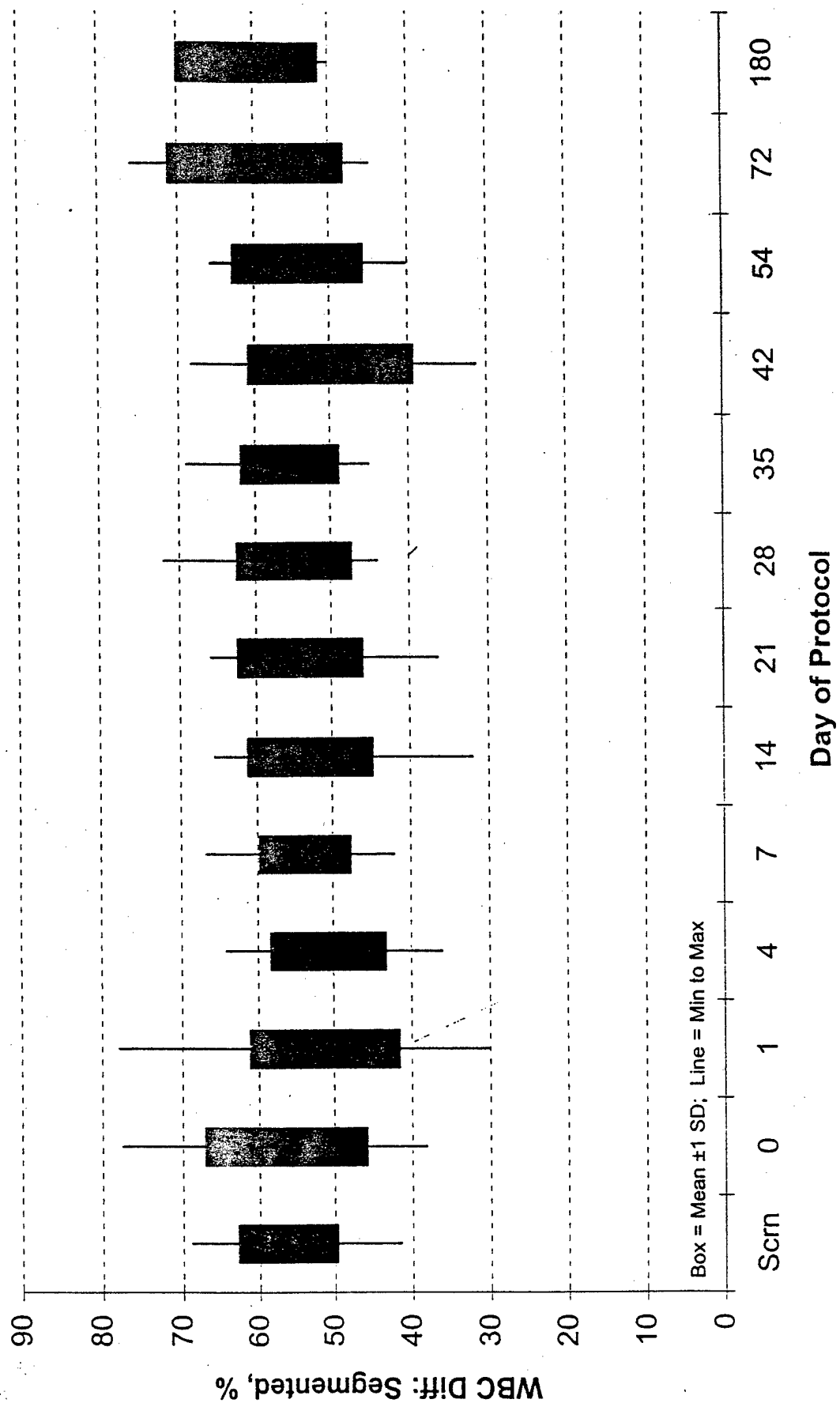
Table 8j  
WBC Differential: Segmented

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	66.0	68.0	51.4	51.7	55.9	57.6	56.3	60.0	57.5	65.1	52.8	52.2	68.0
02	50.0	52.0	46.0	49.2	50.3	45.7	44.0	50.9	56.5	37.5			
03	54.2	53.2	51.0	43.0	63.8	48.5	47.7	44.6	52.2	47.6	57.7	76.0	50.0
04		64.9	57.7	60.3	52.5	59.0	65.1	72.1	61.0				
05	50.1	51.4	45.7	41.0	51.0	59.0	51.0	51.3	57.4				
06	58.0	64.8	54.1	58.0	58.1	60.8	66.2	55.7	59.1	60.9	58.2	70.6	64.0
07	52.0	46.5	48.7	46.4	54.3	53.2	58.0	60.3		53.6	63.0		
08	48.0	38.1	35.1	36.0	42.0								
09	61.1	67.2	61.9	64.4	67.0	53.0	65.7	66.8	69.2	68.5	65.2		
10	51.6	48.3	49.5	57.7	49.0	58.0	63.5	58.8	54.2	49.7	45.6		
11	63.3	77.6	78.0	42.4	52.0	52.2	59.7	58.8		54.7			
12	60.2	53.0	56.5	49.2	51.6	55.8	52.1	55.0	56.0	53.9	55.7		
13	54.4	53.9	42.1	48.2	54.4	46.0	43.9	43.9	46.7	43.6	40.2	57.9	
14	69.0	56.5	56.6	56.0	61.5	59.1	55.9	62.9	65.5				
15	41.4	40.0	47.0	41.8	47.0	38.5	36.3	43.9	44.9	37.0	43.0		
16	60.0	65.0	57.2	54.1	56.3	57.6	62.0	50.3	53.8	53.2			
17	58.9	72.0	54.0										
18	61.4	48.8	46.0	53.0	47.2	46.4	51.0	51.3	45.2	31.2	42.8		
19	53.3	55.3	50.0	51.5	48.3	65.8	45.9	49.6	49.9	58.9	56.1		
20	52.6	43.0	30.0	49.0	51.6	32.0	50.0	48.5	53.1	35.3	66.0	44.7	
21	60.4	66.1	60.1	62.0	59.9	58.9	56.3	59.3	60.0	50.9	59.4	56.5	
Summary:	WBC Diff: Segmented, %												
Average	56.3	56.5	51.4	50.7	53.7	53.0	54.2	54.9	55.4	50.1	54.3	59.7	60.7
Std Dev	06.7	10.8	09.9	07.6	06.1	08.4	08.4	07.8	06.7	10.9	08.8	11.7	09.5
Max	69.0	77.6	78.0	64.4	67.0	65.8	66.2	72.1	69.2	68.5	66.0	76.0	68.0
Min	41.4	38.1	30.0	36.0	42.0	32.0	36.3	43.9	44.9	31.2	40.2	44.7	50.0



Figure 20: SD &amp; Range Charts for WBC Diff: Segmented, %



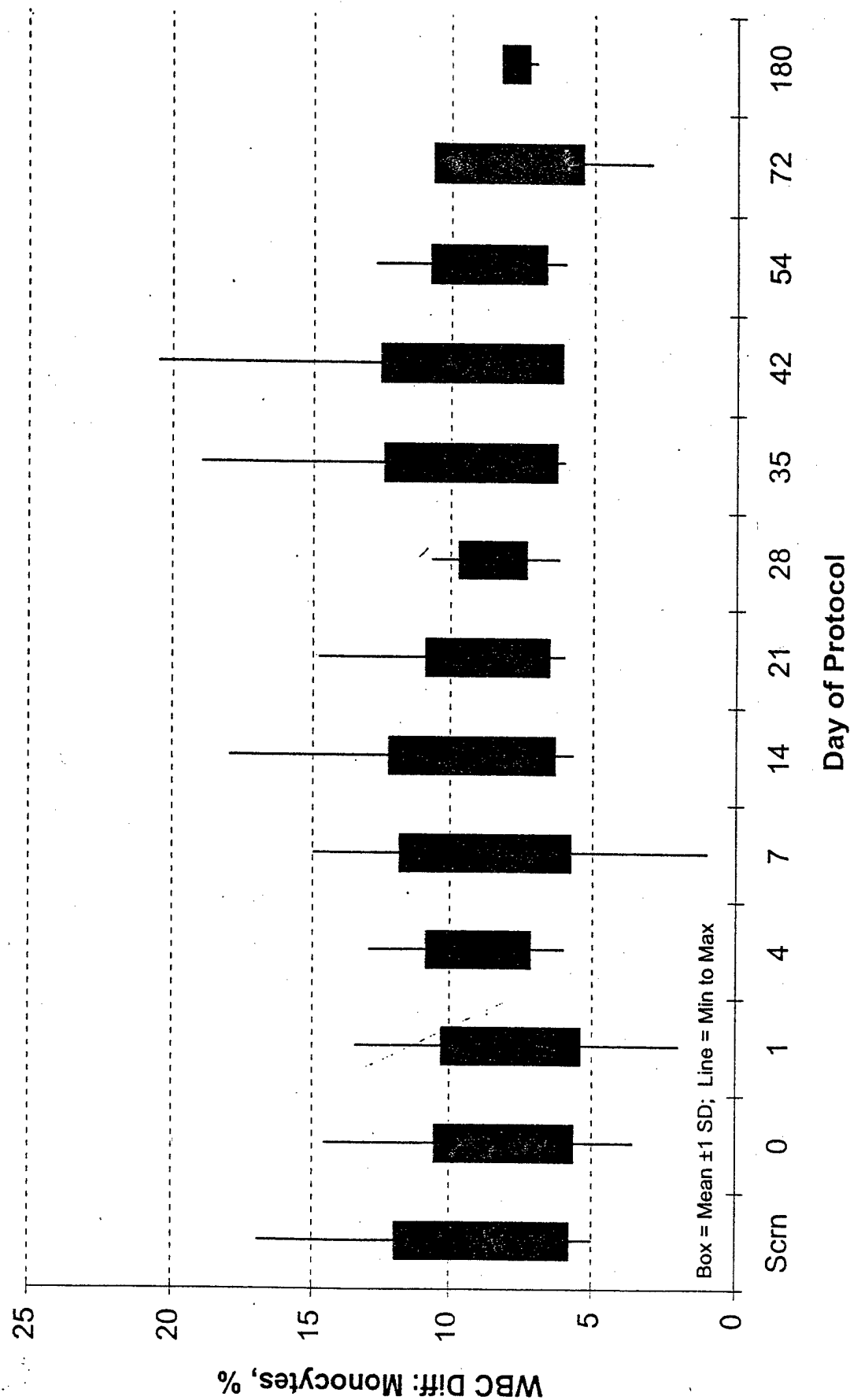
Units: %

Table 8k  
WBC Differential: Monocytes

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	7.0	6.0	8.0	9.7	7.6	7.4	8.7	7.8	8.6	6.2	9.1	9.7	8.0
02	17.0	11.0	2.0	12.8	10.9	13.2	14.8	8.9	19.0	20.5			
03	6.5	7.8	7.0	6.5	6.2	5.7	6.5	6.2	6.5	7.8	6.0	3.0	8.0
04		3.6	6.1	7.5	7.5	6.0	7.4	8.0	6.0				
05	6.8	8.3	8.9	9.0	12.0	7.0	10.0	8.1					
06	7.0	6.7	8.6	8.0	7.4	7.0	7.1	7.5	7.7	8.2	7.1	7.9	7.0
07	9.0	9.5	9.6	10.9	10.2	10.2	10.0	10.7		10.5	7.0		
08	17.0	14.6	13.5	13.0	15.0								
09	10.5	9.5	9.6	8.9	8.0	11.0	8.1	9.4	10.1	8.0	8.6		
10	5.0	8.3	7.8	10.5	1.0	8.1	8.2	8.9	8.9	8.5	12.8		
11	7.5	8.4	6.0	9.3	6.0	8.6	6.6	6.8		8.1			
12	7.6	6.3	8.3	7.1	8.4	7.1	8.2	8.2	8.0	8.3	7.6		
13	9.2	9.4	10.0	8.1	11.8	10.5	9.9	9.9	11.1	10.3	12.6	8.1	
14	10.0	10.8	12.1	11.0	12.6	12.2	12.5	10.2	12.1				
15	7.0	8.4	6.0	8.4	10.0	8.8	7.5	8.4	6.7	7.6	8.0		8.0
16	6.0	5.7	7.4	7.4	6.9	8.4	6.0	7.8	7.4	7.3			
17	10.2	5.0	8.3										
18	9.6	10.6	8.0	6.0	12.0	11.8	11.0	8.8	10.5	9.8	10.0		
19	7.7	7.4	6.0	8.6	7.6	7.2	7.6	7.3	7.9	7.6	7.3		
20	8.7	6.0	7.0	9.0	7.7	18.0	8.0	10.4	10.6	11.4	8.8	10.4	
21	9.1	6.8	4.8	8.6	7.6	8.7	7.6	8.6	9.0	9.6	8.4	9.0	
Summary:	WBC Diff: Monocytes, %												
Average	8.9	8.1	7.9	9.0	8.8	9.3	8.7	8.5	9.4	9.4	8.7	8.0	7.8
Std Dev	3.1	2.5	2.5	1.9	3.1	3.0	2.2	1.2	3.1	3.3	2.0	2.6	0.5
Max	17.0	14.6	13.5	13.0	15.0	18.0	14.8	10.7	19.0	20.5	12.8	10.4	8.0
Min	5.0	3.6	2.0	6.0	1.0	5.7	6.0	6.2	6.0	6.2	6.0	3.0	7.0

Figure 21: SD &amp; Range Charts for WBC Diff: Monocytes, %



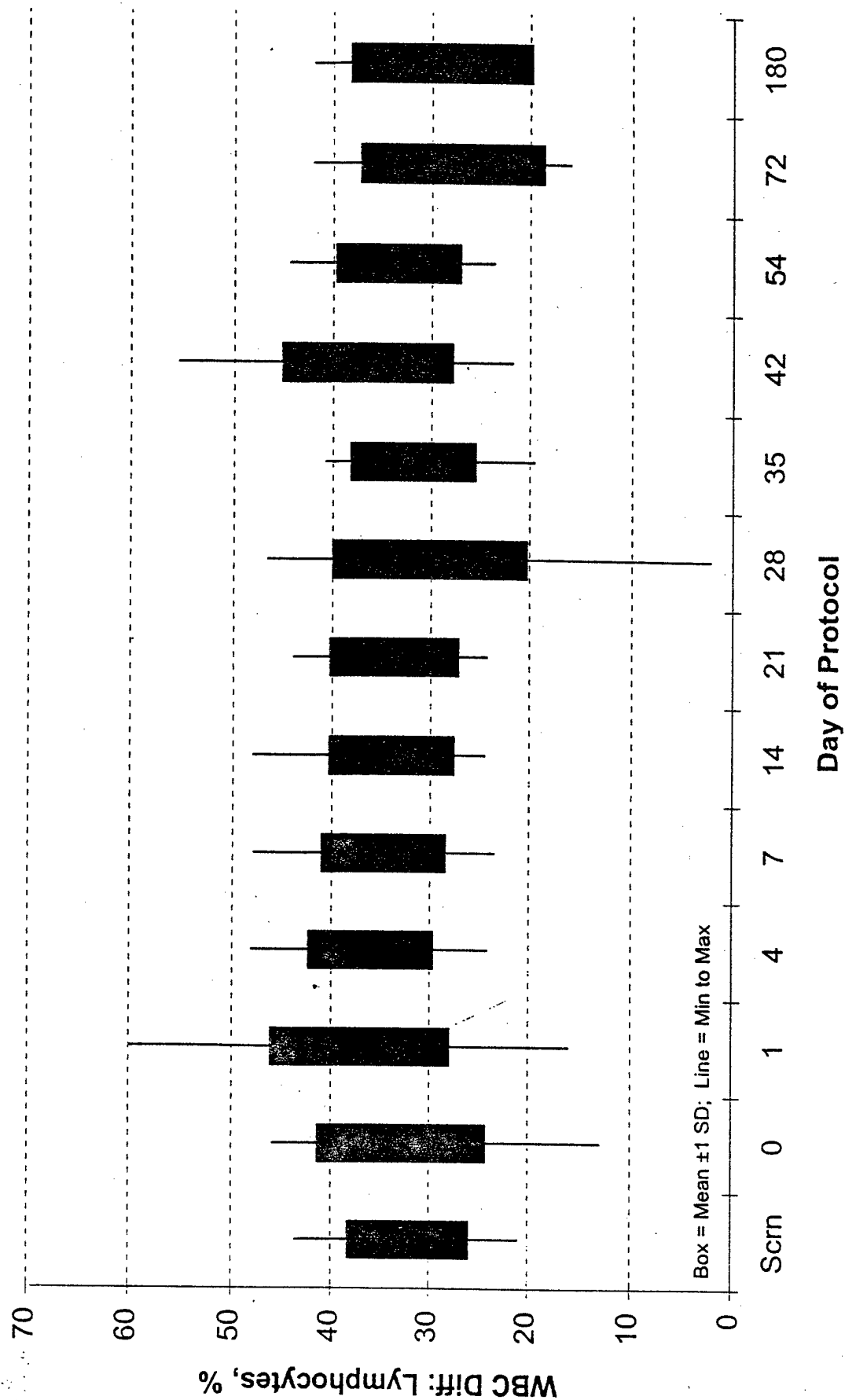
Units: %

Table 8L  
WBC Differential: Lymphocytes

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	27.0	26.0	35.5	33.0	39.5	29.1	28.3	26.2	28.2	25.4	34.1	31.6	24.0
02	33.0	37.0	48.0	31.9	33.5	35.2	35.0	34.0	23.8	39.6			
03	37.7	37.7	40.7	48.2	28.3	43.3	43.3	46.7	39.4	42.9	32.9	16.0	42.0
04		30.2	34.1	30.9	38.8	35.0	26.2	18.5	33.0				
05	38.4	34.1	39.4	45.0	37.0	34.0	34.9	31.0					
06	35.0	27.6	35.1	34.0	32.5	29.4	24.5	33.7	30.6	28.1	33.0	19.1	29.0
07	39.0	40.9	38.1	36.2	31.1	30.2	32.0	24.4		32.3	28.0		
08	31.0	41.7	45.0	34.0	43.0								
09	27.2	22.2	26.0	24.2	23.5	27.0	24.3	21.2	19.5	21.7	24.9		
10	38.5	40.9	39.6	30.2	48.0	32.0	26.2	28.7	32.1	38.7	39.2		
11	26.3	12.9	16.0	44.0	42.0	35.5	30.3	2.2		31.5			
12	30.9	39.6	33.2	39.8	37.0	34.9	37.7	34.9	36.0	35.9	34.5		
13	33.6	35.2	43.6	39.1	30.6	39.6	42.6	42.6	37.8	40.9	42.5	29.2	
14	21.0	31.0	29.2	29.0	24.2	26.5	28.9	21.9	19.8				21.0
15	43.7	46.0	37.0	41.7	31.0	42.6	44.0	31.0	32.0	39.9	37.0		
16	34.0	26.7	32.0	35.2	31.5	30.0	31.0	35.7	34.4	35.7			
17	21.2	22.0	29.5										
18	26.0	36.6	44.0	40.0	36.9	48.1	38.0	36.1	40.8	55.4	44.5		
19	35.9	33.1	44.0	36.1	40.2	24.5	42.9	39.1	37.5	29.9	32.3		
20	36.4	45.0	60.0	42.0	37.9	40.0	38.0	36.1	34.0	50.5	23.6	42.1	
21	27.8	24.0	29.1	26.2	28.8	28.7	32.7	28.6	31.0	35.8	27.6	29.5	
Summary:	WBC Diff: Lymphocytes, %												
Average	32.2	32.9	37.1	36.0	34.8	34.0	33.7	30.1	31.9	36.5	33.4	27.9	29.0
Std Dev	6.2	8.6	9.2	6.4	6.4	6.4	6.6	9.9	6.4	8.7	6.4	9.4	9.3
Max	43.7	46.0	60.0	48.2	48.0	48.1	44.0	46.7	40.8	55.4	44.5	42.1	42.0
Min	21.0	12.9	16.0	24.2	23.5	24.5	24.3	2.2	19.5	21.7	23.6	16.0	21.0

Figure 22: SD &amp; Range Charts for WBC Diff: Lymphocytes, %



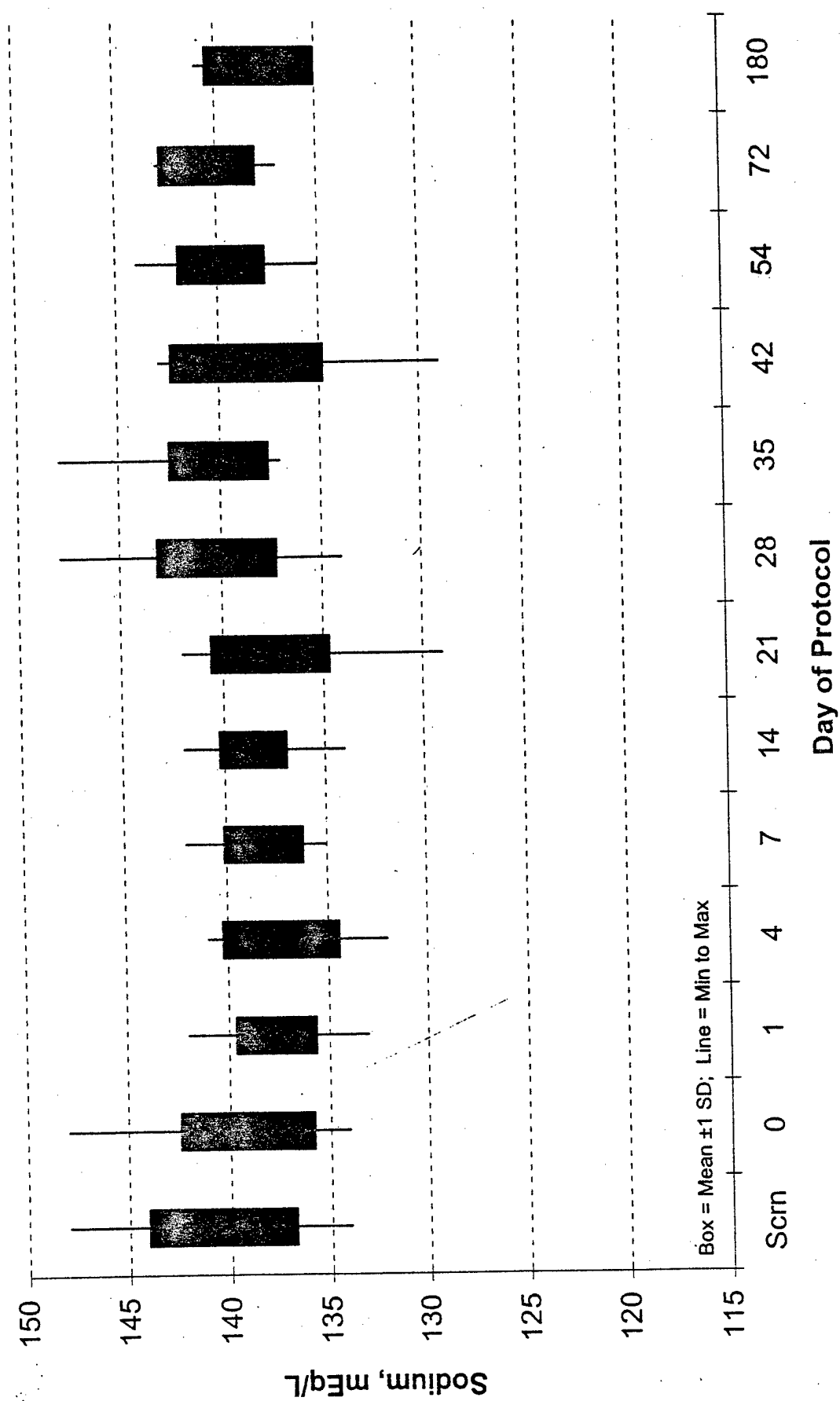
Units: mEq/L

Table 9a  
Sodium

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	138	136	137	140	137	140	140	140	142	140	141	139	141
02	136	136	138	138	137	138	136	148	148	129			
03	140	140	141	136	136	134		140	140	141	140	142	139
04	141	141	138	134	139	139		141	138				
05	142		136	139	142	142	142	142					
06	142	142	137	141	138	139	141	140	140	138	140	137	135
07	136		133	132	138	139	140	143	138	141	141		
08	147	138	137	135	137								
09	148	141	142	138	139	139	140	142	140	143	142		
10	137	134	137	132	135	137	135	137	138	138	135		
11	145	135	135	138	137	140	139	138					
12	137	139		140	141	141	136	140	138	140	141		
13	140	148	139	141	142	139	138	134	140	139	141		
14	141	138	136	137	137	137	136	140	140				
15	140	139	139	141	141	138	139	140	139	142	139		136
16	141	141	138	141	139	138	138	140	140	143	139		
17		140	139										
18	134	135	137	134	137	137	136	141	141	133	138		
19	141	142	137	138	136	138	129	141	137		138		
20	138	139	140	137	138	139	138	142	140	135	138	141	
21	144		137	135	137	139	137	135	142	139	144	143	
Summary:	Sodium, mEq/L												
Average	140	139	138	137	138	139	138	140	140	139	140	140	138
Std Dev	04	03	02	03	02	02	03	03	02	04	02	02	03
Max	148	148	142	141	142	142	142	148	148	143	144	143	141
Min	134	134	133	132	135	134	129	134	137	129	135	137	135

Figure 23: SD &amp; Range Charts for Sodium, mEq/L



Units: mEq/L

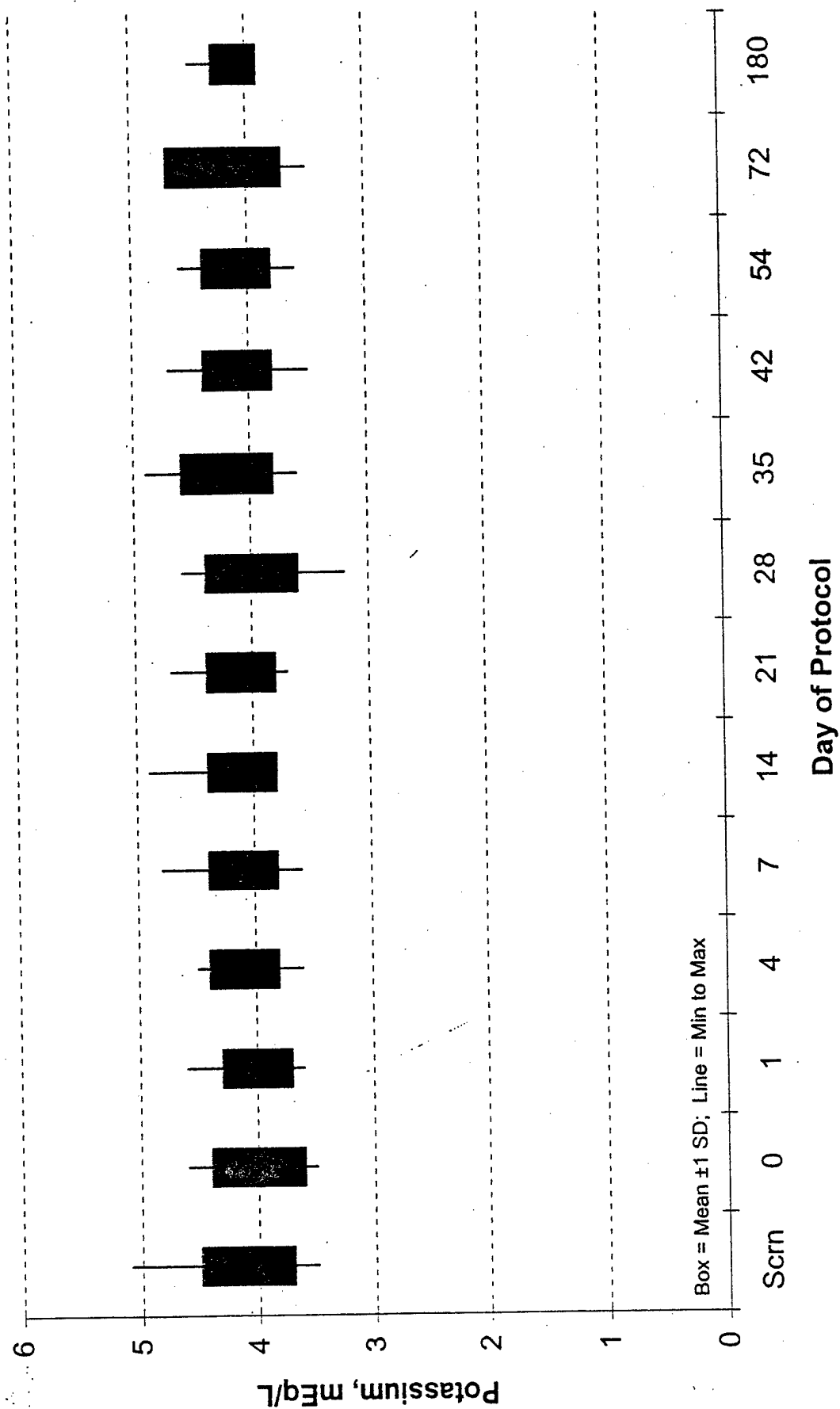
Table 9b  
Potassium

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	3.9	3.5	3.9	3.7	3.6	3.8	3.7	3.3	3.7	3.8	3.6	3.7	4.0
02	4.1	4.1	4.4	4.2	3.9	4.0	4.1	3.9	3.6	4.5			
03	3.8	4.3	4.3	4.5	4.1	4.2	4.2	4.2	4.1	4.7	4.1	4.4	4.2
04	3.7	3.5	4.5	3.9	4.2	3.9		4.6	4.4				
05	3.7		4.1	3.6	3.8	3.8	3.7	4.0			4.3		
06	4.5	4.9	3.9	4.0	3.8	3.9	4.2	4.2	4.0	4.0	4.3	4.4	3.9
07	4.6		3.8	3.8	4.3	4.2	4.7	4.4	4.9	4.1	4.4		
08	4.5	4.0	3.6	3.9	4.1								
09	4.1	4.0	3.9	3.8	4.1	4.0	4.0	4.3	4.0	4.2	4.3		
10	3.5	3.7	3.9	4.0	4.0	4.2	4.0	3.9	4.0	4.3	4.0		
11	3.8	3.9	3.7	4.0	4.1	4.0	3.9	3.7	3.7	3.9			
12	4.0	4.6		4.1	4.4	4.3	4.3	4.1	4.3	4.1	3.9		
13	4.4	4.1	4.0	3.8	3.9	3.9	4.1	3.6	3.7	4.4	3.8		
14	4.2	3.6	4.0	4.2	4.8	4.3	4.6	4.1	4.3				4.1
15	3.9	3.5	3.6	3.9	4.1	4.0	4.1	4.3	4.6	3.8	4.1	4.7	
16	5.1	4.3	4.3	4.5	4.2	4.9	4.3	4.4	4.6	4.4			
17		3.8	3.6										
18	4.6	4.4	4.6	4.5	4.1	4.2	4.2	4.2	4.5	4.2	4.5		
19	4.0	4.2	3.8	4.2	4.1	4.4	4.0	4.2	4.2		4.0	3.5	4.2
20	3.6	3.7	3.8	4.1	3.6	4.3	4.2	3.2	3.7	3.5	4.0	4.7	4.1
21	4.5	3.8		4.5	4.1	4.3	4.2	4.3	4.4	4.2	4.6		4.5
Summary:	Potassium, mEq/L												
Average	4.1	4.0	4.0	4.1	4.1	4.1	4.1	4.0	4.2	4.1	4.1	4.2	4.1
Std Dev	0.4	0.4	0.3	0.3	0.3	0.3	0.3	0.4	0.4	0.3	0.3	0.5	0.2
Max	5.1	4.6	4.6	4.5	4.8	4.9	4.7	4.6	4.9	4.7	4.6	4.7	4.5
Min	3.5	3.5	3.6	3.6	3.6	3.8	3.7	3.2	3.6	3.5	3.6	3.5	3.9



Figure 24: SD & Range Charts for Potassium, mEq/L



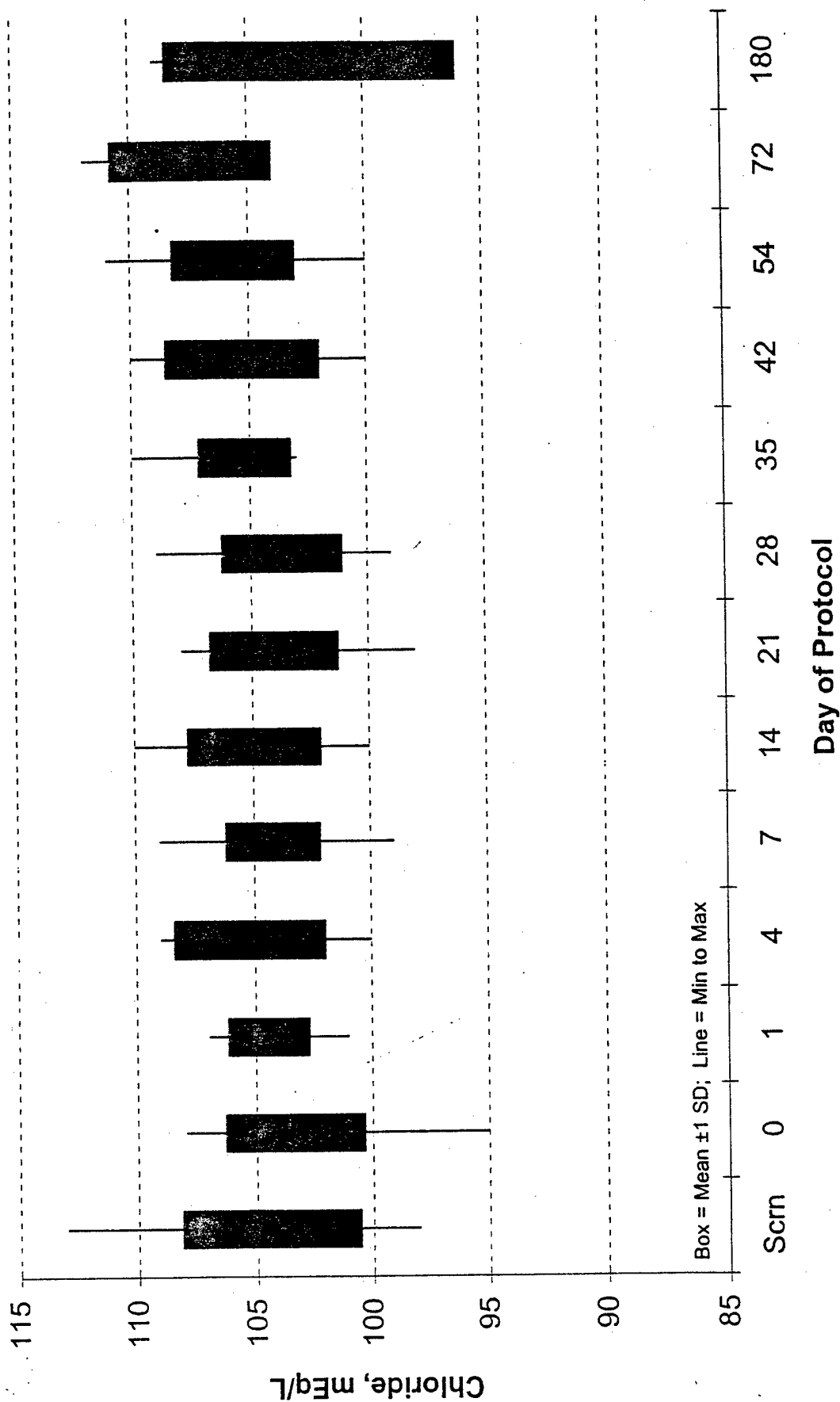
Units: mEq/L

Table 9c  
Chloride

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	98	95	101	101	103	105	99	102	105	101	105	108	106
02	100	99	105	103	103	100	98	101	103				
03	107	106	103	105	107	102		104	110	106	106	112	109
04	103	103	104	101	105	105		104	104				
05	106		104	108	109	108	108	106					
06	103	108	107	106	104	106	105	102	105	100	103	104	98
07	102		106	109	104	108	102	108	105	105	106		
08	113	105	104	108	104					104	106		
09	113	106	107	108	105	109	105	104	106	108	103		
10	102	102	106	107	105	109	104	105	106	108			
11	109	106	106	108	104	110	104	104	105	107	105		
12	103	104		104	105	103	106	105	105	100	106		
13	102	103	103	109	104	104	102	99	105	100			
14	104	104	103	108	103	105	106	103	103	110	108		96
15	103	102	103	107	103	105	106	109	109	110	108		
16	102	106	107	108	107	104	106	109					
17		101	106								100		
18	102	102	105	100	104	104	101	102	103	106	111		
19	104	104	104	102	99	104	105	102	106				
20	106	104	103	100	102	103	105	103	103	104	107	104	
21	105		102	102	104	100	107	100	105	105	105	109	
Summary:	Chloride, mEq/L												
Average	104	103	104	105	104	105	104	104	105	105	106	107	102
Std Dev	04	03	02	03	02	03	03	03	02	03	03	03	06
Max	113	108	107	109	109	110	108	109	110	110	111	112	109
Min	98	95	101	100	99	100	98	99	103	100	100	104	96

Figure 25: SD & Range Charts for Chloride, mEq/L

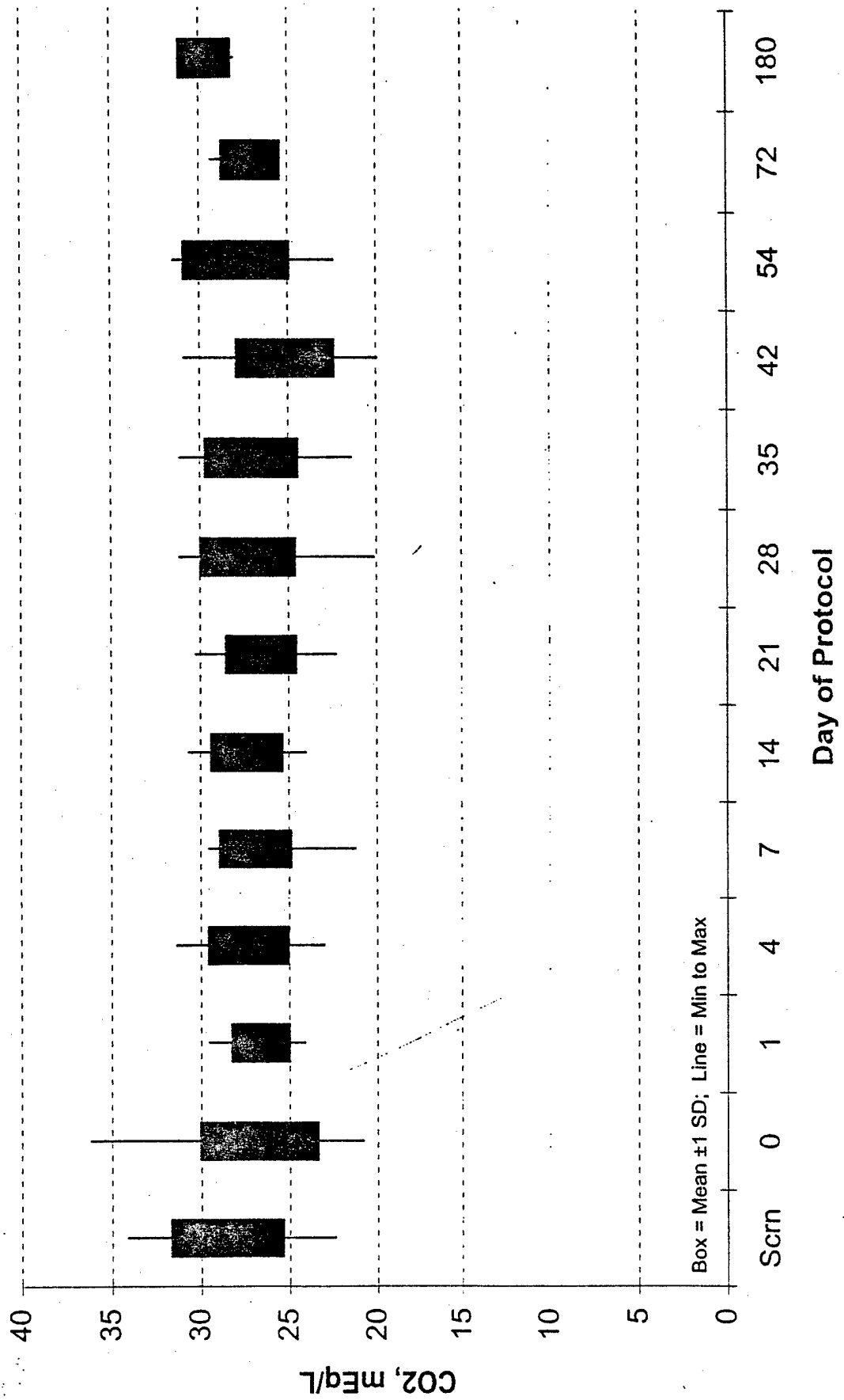


Units: mEq/L

Table 9d  
CO<sub>2</sub>

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	34.2	26.4	28.8	29.8	29.5	26.9	29.0	31.2	25.4	26.3	29.9	28.0	30.9
02	27.1	27.7	26.0	28.5	29.4	30.0	28.2	29.3	26.7				
03	28.0	29.4	29.6	25.3	25.5	24.6		28.7	25.7	19.9	22.4	25.4	28.0
04	24.6	36.2	27.1	27.2	27.1	28.5		25.3	29.0				
05	29.6		25.9	28.3	28.4	29.2	27.1	30.6					
06	33.2	27.1	27.9	31.4	26.7	28.0	28.2	27.9	31.2	23.1	31.2	27.3	30.1
07	31.0		27.8	23.7	26.9	28.0	25.1	29.7	26.0	29.3	25.6		
08	25.4	25.5	26.2	29.7	25.3								
09	25.2	29.5	28.3	27.2	26.0	27.8	26.7	29.6	30.4	30.9	27.5		
10	22.4	20.8	24.1	23.0	21.2	24.3	24.2	24.9	23.2	24.1	22.4		
11	24.2	26.1	27.6	26.9	29.6	28.3	26.1	25.8		26.4			
12	29.2	26.0		24.0	29.0	28.4	24.9	28.5	28.6	25.2	28.8		
13	27.4	28.9	27.7	28.3	27.8	30.7	28.1	26.1	25.0	25.5	29.0		
14	29.1	22.3	24.5	24.3	26.1	24.0	22.3	23.5	21.4				
15	31.1	27.7	29.2	29.6	27.9	25.0	25.5	29.8	27.6	25.5	31.5		
16	33.7	22.0	24.8	26.8	24.2	30.0	26.9	26.4	24.6	23.6	28.9		
17		26.9	26.5										
18	27.7	27.1	25.4	28.2	28.0	24.2	24.1	26.8	29.9	27.0	29.3		
19	29.1	25.9	26.3	27.5	28.5	27.3	28.3	28.5	29.3				
20	28.7	25.5	24.3	26.8	24.9	27.2	26.9	20.1	28.8	23.5	25.7	25.4	
21	29.5		24.8	29.8	26.3	27.9	30.3	26.1	27.6	22.2	30.5	29.4	
Summary:	CO <sub>2</sub> , mEq/L												
Average	28.5	26.7	26.6	27.3	26.9	27.4	26.6	27.3	27.1	25.2	27.9	27.1	29.7
Std Dev	03.2	03.4	01.7	02.3	02.1	02.1	02.1	02.7	02.7	02.8	03.0	01.7	01.5
Max	34.2	36.2	29.6	31.4	29.6	30.7	30.3	31.2	31.2	30.9	31.5	29.4	30.9
Min	22.4	20.8	24.1	23.0	21.2	24.0	22.3	20.1	21.4	19.9	22.4	25.4	28.0

Figure 26: SD & Range Charts for CO<sub>2</sub>, mEq/L

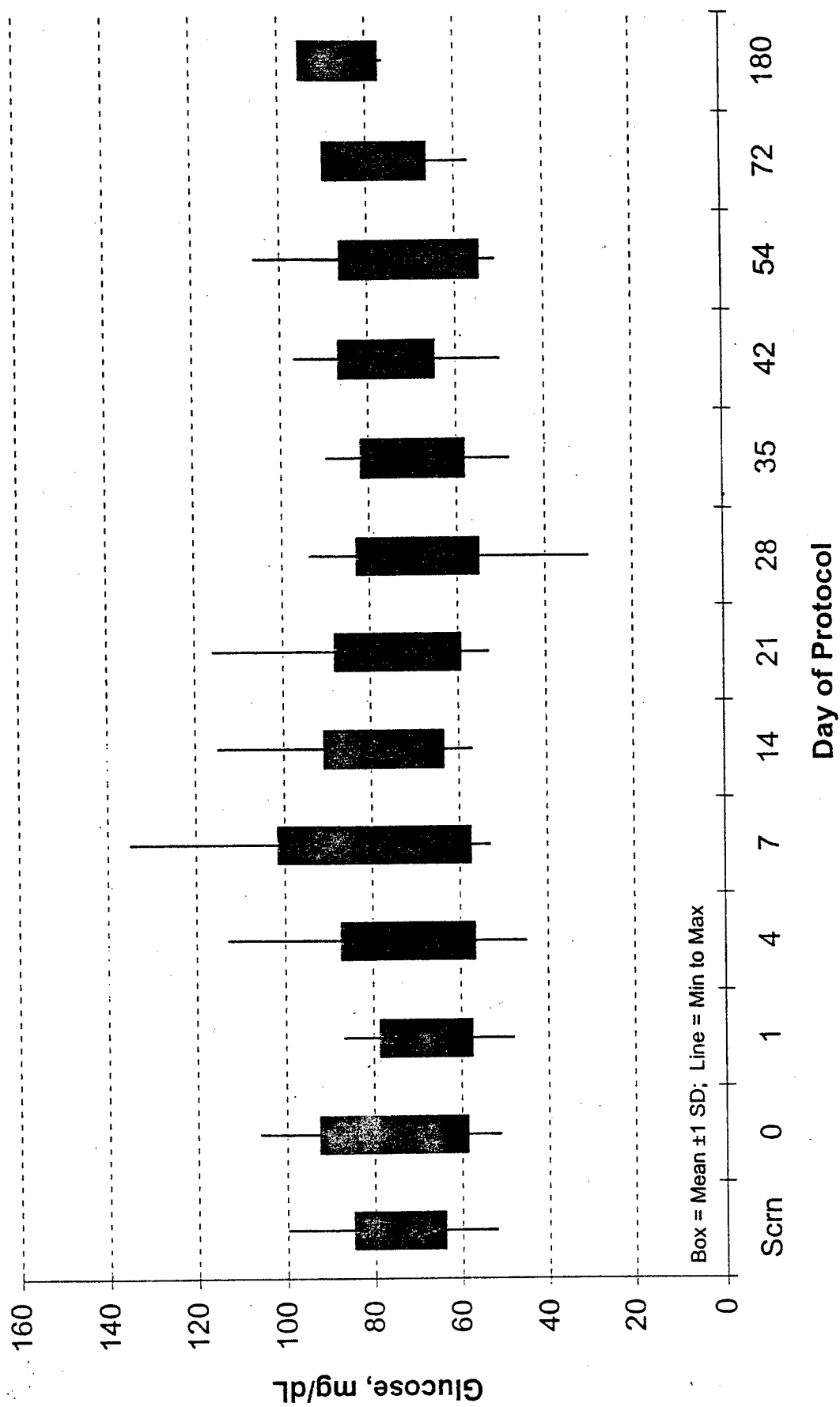
Units: mg/dL

Table 9e  
Glucose

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	78	89	70	74	83	91	58	60	63	50	73	83	81
02	75	82	76	72	94	70	53	56	86				
03	71	67	76	74	85	73		75	75	77	52	86	76
04	78	106	76	83	84	91		76	75				
05	84		60	92	69	82	69	82					
06	80	98	75	57	76	57	82	59	90	74	64	80	95
07	70		65	61	67	84	78	94	57	83	74		
08	87	77	53	67	53								
09	67	54	56	63	55	64	60	60	72	66	51		
10	100	93	81	80	62	115	82	75	88	97	64		
11	79	80	87	86	74	67	64	68		85			
12	84	60		45	89	67	83	83	78	81	86		
13	70	58	64	75	55	77	74	83	65	74	106		
14	62	67	58	113	89	71	77	65	48				
15	64	52	53	67	54	62	116	54	60	62	58		93
16	82	66	65	84	92	78	61	76	75	76	89		
17		51	75										
18	66	83	76	74	125	97	63	68	54	82	69		
19	71	98	70	64	135	75	73	75	68				
20	68	80	48	48	61	77	80	30	62	75	76	57	
21	52		77	62	88	69	83	73	74	80	55	85	
Summary:	Glucose, mg/dL												
Average	74	76	68	72	80	77	74	69	70	76	71	78	86
Std Dev	11	17	11	16	22	14	15	14	12	11	16	12	09
Max	100	106	87	113	135	115	116	94	90	97	106	86	95
Min	52	51	48	45	53	57	53	30	48	50	51	57	76

Figure 27: SD &amp; Range Charts for Glucose, mg/dL



Units: IU/L

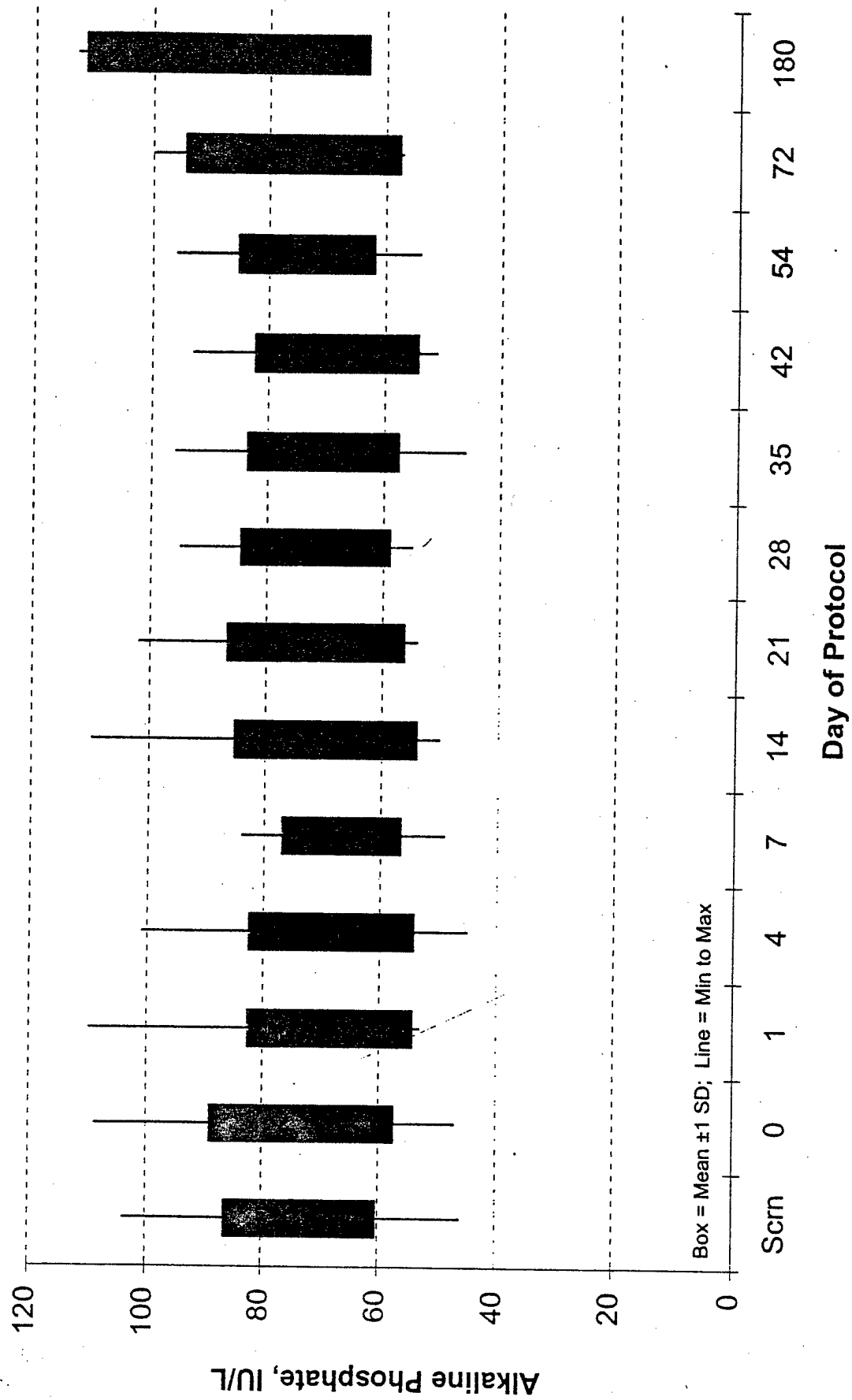
Table 10a  
Alkaline Phosphatase

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	91	100	89	83	79	90	94	77	88	90	87	88	113
02	81	86	77	80	75	86	81	95	70				
03	46	47	59	45	49	50	54	55	46	51	64	59	65
04	65	62	54		56	55		58	66				
05	63		55	55	59	57	60	70					
06	77	75	72	67	70	71	77	93	96	93	96	100	103
07	89		70	83	74	72	69	84	73	77	80		
08	65	60	56	53	53								
09	67	65	64	69	68	65	73	66	58	61	67		
10	84	78	72	69	74	85	77	81	87	86	85		
11	104	109	110	101	84	110	102		83		84		
12	67	55		53	56	59		65	65	65	64		
13	68	65	57	55	60	64	65	63	58	64	54		
14	71	77	75	76	76	65	58	59					68
15	72	57	53	56	55	52	55		65	53	67		
16	86	83	80	85	82	88	100	89	80	70	78		
17		81											
18	61	61	60	64	64	59	57	63	66	63	78		
19	78	79	70	75	72	75	69	75	76		81		
20	73	78	71	72	69	62	65	70	66	62	69	76	
21	61		57	58	60	58	59	56	56	53	60	57	
Summary:	Alkaline Phosphate, IU/L												
Average	73	73	68	68	67	70	71	72	71	68	74	76	87
Std Dev	13	16	14	14	10	16	15	13	13	14	12	19	24
Max	104	109	110	101	84	110	102	95	96	93	96	100	113
Min	46	47	53	45	49	50	54	55	46	51	54	57	65



Figure 28: SD &amp; Range Charts for Alkaline Phosphate, IU/L



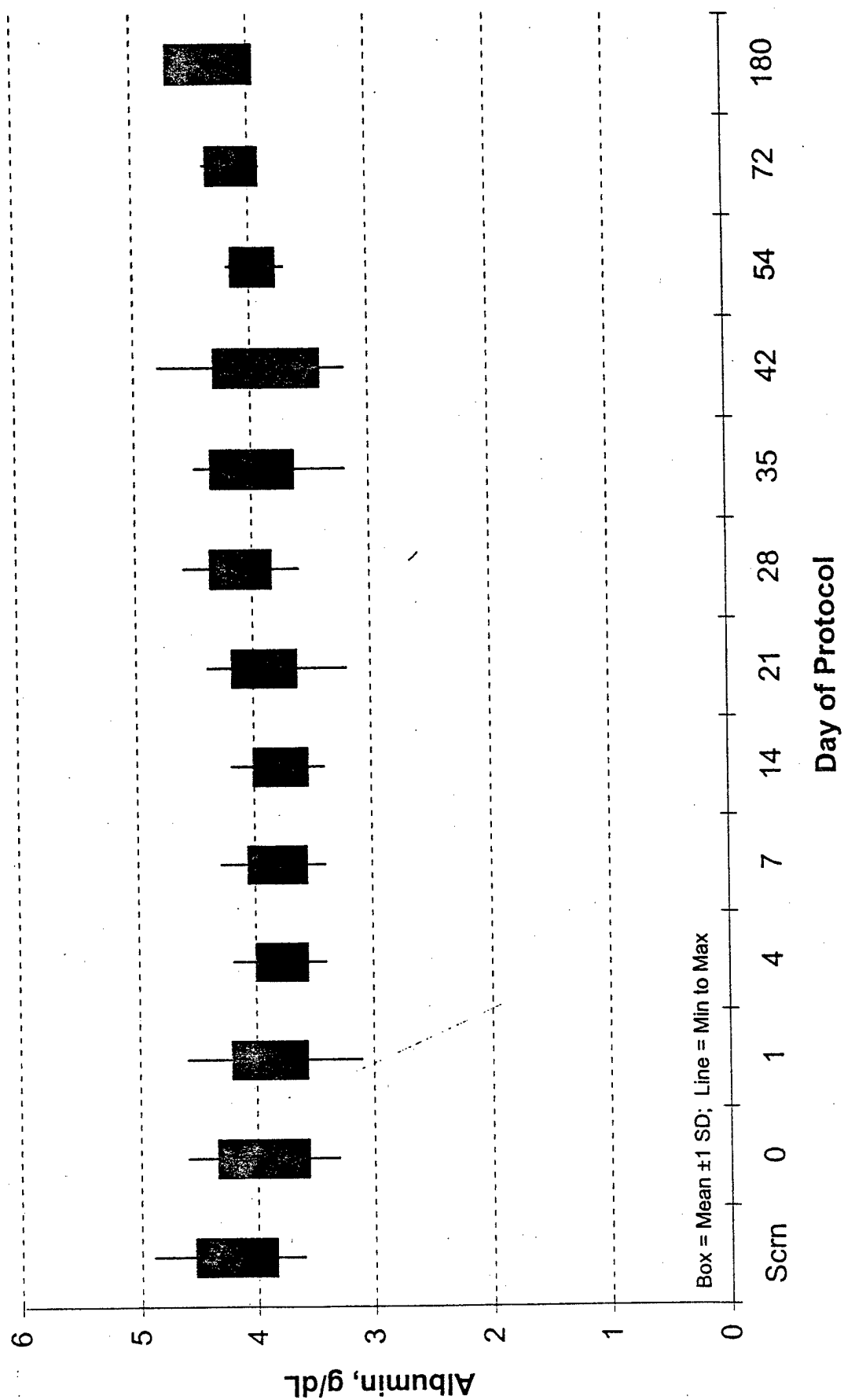
Units: g/dL

Table 10b  
Albumin

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	4.50	4.60	4.10	4.00	3.70	4.10	4.40	3.90	4.40	4.20	4.20	4.30	4.00
02	4.10	3.60	3.70	3.80	4.20	4.20	4.00	4.00	3.70				
03	4.00	3.70	4.10	3.40	3.40	3.60	4.00	4.30	3.80	4.10	3.70	3.90	4.00
04	4.50	4.10	4.30	4.00	3.90	3.70		4.20	4.30				
05	4.10	3.60	3.70	3.60	3.60	3.70	3.90	4.60					
06	4.30	4.50	4.30	3.90	4.10	3.70	4.20	4.30	4.50	4.20	4.10	3.90	4.60
07	4.30	3.90	3.90	3.90	4.30		4.10	4.20	4.10	4.10	4.10		
08	4.40	4.10	3.80	3.80	3.90								
09	3.80	3.40	3.60	3.60	3.60	3.40	3.80	3.70	3.20	3.60	3.70		
10	3.80	3.70	3.60	3.60	3.50	3.50	3.20	3.70	3.70	3.30	3.80		
11	3.80	3.70	3.90	3.50	3.80	3.70	3.60	3.90	3.50				
12	4.80	4.60	4.60	3.80	3.90	3.90	4.00	4.20	4.20	4.00	3.90		
13	4.20	4.40	3.90	3.60	3.80	3.60	4.00	4.00	4.30	4.80	4.20		
14	3.60	3.30	3.10	3.50	3.70		3.60	3.60	3.60				
15	4.90	4.10	3.80	4.00	4.00	3.80	4.00	4.30	4.30	3.20	3.70		4.70
16	3.80	3.70	3.50	3.60	3.40				3.70				
17			4.20										
18	3.80	3.70	3.60	3.70	3.50	3.50	3.60		3.90	3.40	4.20		
19	4.30	4.30	4.00	4.10	3.90	4.00	3.90	4.20	4.30		4.00		
20	4.50	4.10	4.00	4.20	3.90	3.90	3.90	4.40	4.20	3.70	4.10	4.40	
21	4.30		4.00	4.00	4.10	4.10	4.20	4.20	4.20	3.80	3.90	4.20	
Summary:	Albumin, g/dL												
Average	4.19	3.95	3.89	3.78	3.81	3.78	3.91	4.10	3.99	3.87	3.97	4.14	4.33
Std Dev	0.36	0.40	0.33	0.23	0.26	0.24	0.28	0.27	0.37	0.46	0.20	0.23	0.38
Max	4.90	4.60	4.60	4.20	4.30	4.20	4.40	4.60	4.50	4.80	4.20	4.40	4.70
Min	3.60	3.30	3.10	3.40	3.40	3.40	3.20	3.60	3.20	3.20	3.70	3.90	4.00

Figure 29: SD &amp; Range Charts for Albumin, g/dL



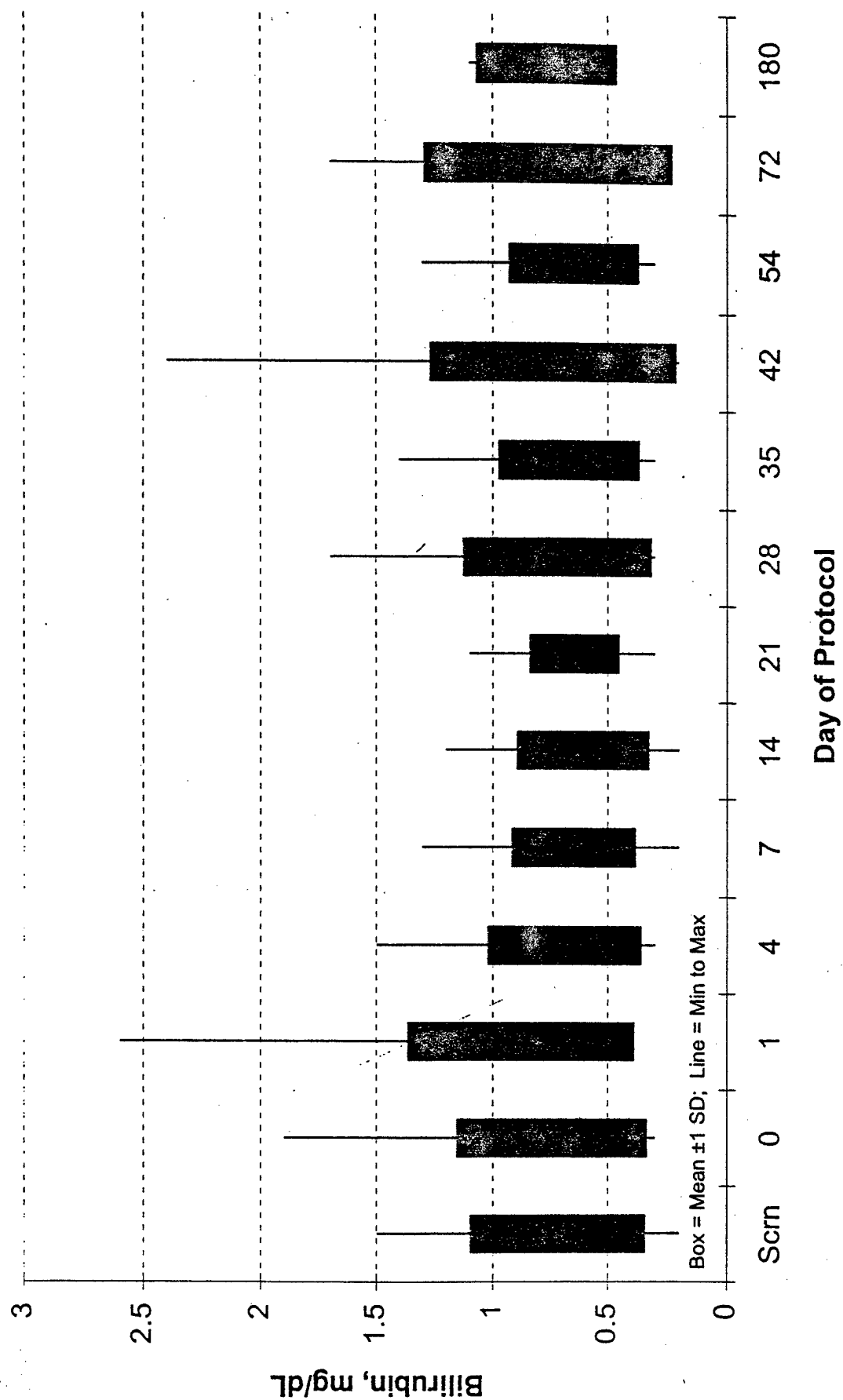
Units: mg/dL

Table 10c  
Bilirubin

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	0.4	0.6	0.8	0.5	0.6	0.5	0.7	0.6	0.6	0.7	0.5	0.4	0.70
02	0.6	0.7	0.5	0.5	0.6	0.5	0.5	0.7	0.4				
03	0.5	0.6	0.9	0.5	0.6	0.4		0.7	0.4	0.7	0.3	0.5	0.50
04	0.5	0.6	0.6	0.4	0.4	0.4		0.3	0.4	0.5			
05	0.6		0.5	0.6	0.5	0.6	0.6	0.6					
06	1.0	0.8	1.1	0.4	0.7	0.7	0.8	0.8	0.8	1.3	0.8	0.6	1.10
07	0.6		0.7	0.3	0.4	0.2	0.4	0.5	0.4	0.5	0.4		
08	0.5	0.6	0.6	0.5	0.5								
09	0.6	0.6	0.6	0.9	0.7	0.6	0.8	0.3	0.5	0.5	0.6		
10	0.2	0.3	0.4	0.4	0.3	0.2	0.4	0.3	0.3	0.2	0.3		
11	0.7	0.3	0.6	0.4	0.6	0.6	0.9	0.5		0.5			
12	1.3	1.1		1.0	0.7	0.9	0.6	0.9	0.8	0.9	0.8		
13	1.5	1.9	2.6	1.5	1.3	1.1	0.8	1.7	1.4	2.4	1.1		
14	0.8	0.7	1.0	0.8	0.7	0.6	0.6	1.0	1.0				
15	1.0	0.5	0.8	0.8	0.7	0.9	0.6	0.8	0.7	0.5	0.6		
16	0.3	0.5	0.8	0.8	0.7	0.9	0.6	0.8	0.7	0.5	0.6		
17		0.8	1.0										
18	0.4	0.5	0.6	0.4	0.2	0.2	0.3	0.3	0.5	0.4	0.5		
19	1.0	0.7	1.0	0.9	0.7	0.6	0.6	0.8	0.8		0.7		
20	1.5	1.6	1.6	1.4	1.3	1.2	1.1	1.7	1.2	0.9	1.3	1.7	
21	0.4		0.8	0.8	0.8	0.5	0.7	0.4	0.5	0.6	0.6	0.6	
Summary:	Bilirubin, mg/dL												
Average	0.7	0.7	0.9	0.7	0.7	0.6	0.6	0.7	0.7	0.7	0.7	0.8	0.77
Std Dev	0.4	0.4	0.5	0.3	0.3	0.3	0.2	0.4	0.3	0.5	0.3	0.5	0.31
Max	1.5	1.9	2.6	1.5	1.3	1.2	1.1	1.7	1.4	2.4	1.3	1.7	1.10
Min	0.2	0.3	0.4	0.3	0.2	0.2	0.3	0.3	0.3	0.2	0.3	0.4	0.50

Figure 30: SD & Range Charts for Bilirubin, mg/dL



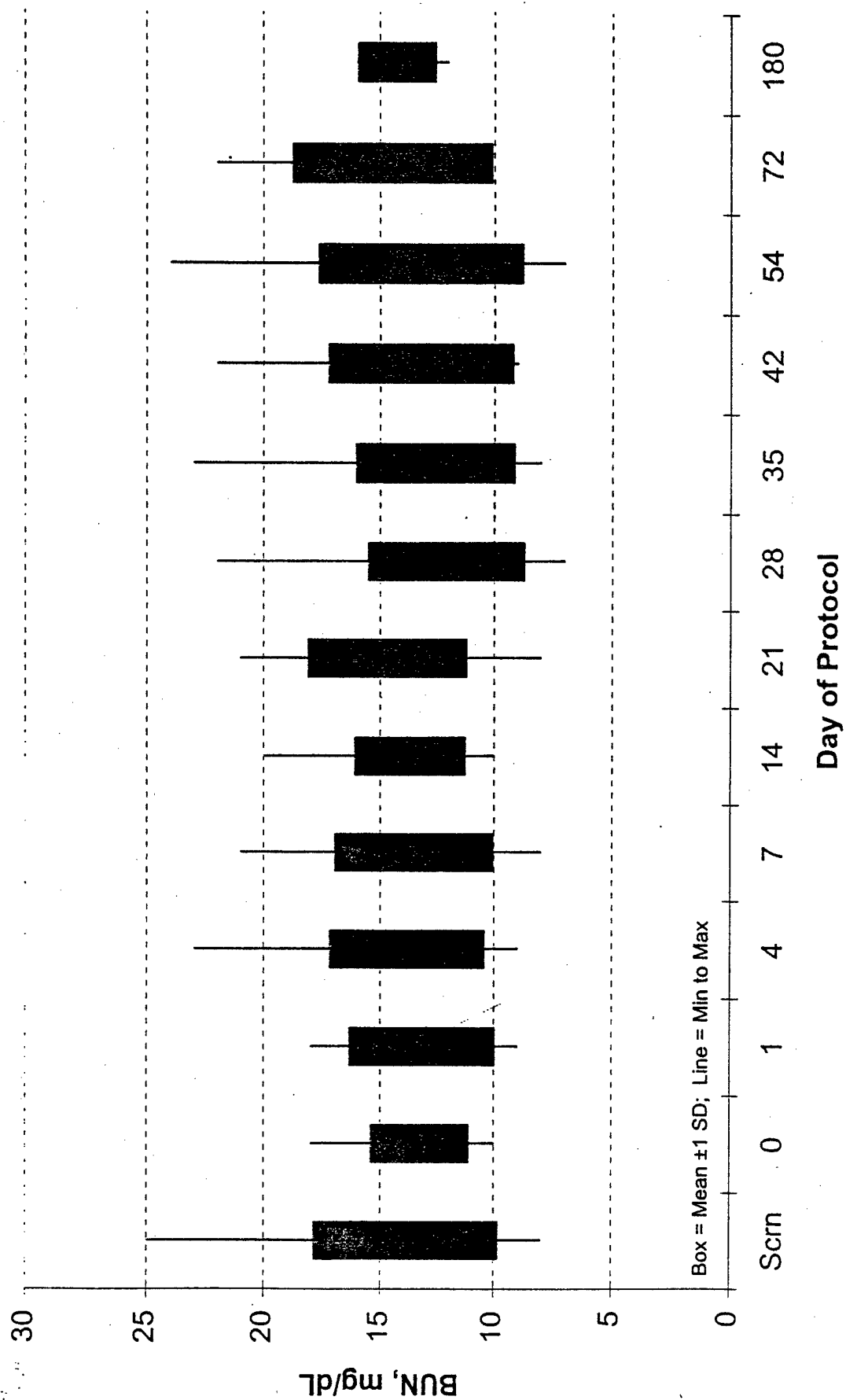
Units: mg/dL

Table 10d  
BUN

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	16	14	17	10	17	14	18	13	16	15	15	12	12
02	19	10	10	12	11	12	18	9	8				
03	14	17	16	12	11	12		12	12	15	14	12	15
04	14.8	11.2	16	14	15	11		13	12				
05	9		14	12	12	13	12	8					
06	11	14	16	18	16	14	15	13	12	17	15	12	14
07	20		10	15	16	20	21	16	10	16	13		
08	13	14	18	18	20								
09	14	12	11	14	13	15	14	13	15	18	12		
10	15	11	11	9	10	18	12	7	12	13	8		
11	13	12	10	13	10	13	8	10		9			
12	10	15		12	12	14	14	11	12	10	11		
13	13	14	17	14	13	13	13	11	13	9	19		
14	12	14	12	12	11	13	15	15	15				
15	12	13	11	13	13	12	11	11	11	10	11		16
16	10	14	13	17	14	13	15	15	12	10	15		
17		10.5	9										
18	8	14	9	11	8	10	14	12	10	11	7		
19	16	18	15	17	17	14	18	11	13		12		
20	12	11	10	10	10	12	11	8.3	8	10	9	14.1	
21	25		18	23	21	17	20	22	23	22	24	22	
Summary:	BUN, mg/dL												
Average	14	13	13	14	14	14	15	12	13	13	13	14	14
Std Dev	04	02	03	03	03	02	03	03	03	04	04	04	02
Max	25	18	18	23	21	20	21	22	23	22	24	22	16
Min	08	10	09	09	08	10	08	07	08	09	07	12	12

Figure 31: SD &amp; Range Charts for BUN, mg/dL



Units: mg/dL

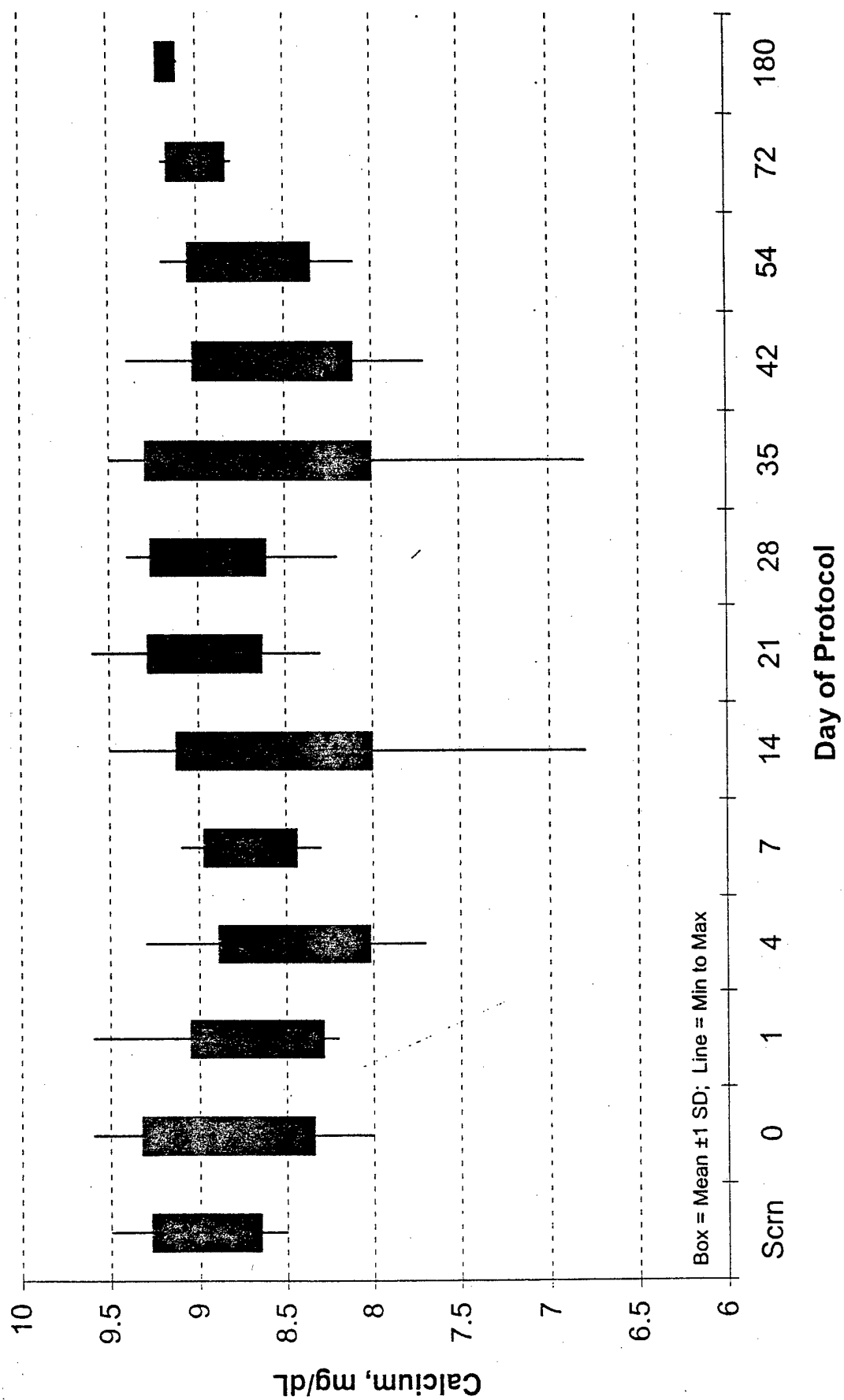
Table 10e  
Calcium

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	9.40	9.30	8.90	8.50	8.70	8.80	9.10	8.80	9.10	8.30	8.60	8.90	9.20
02	9.20	9.20	9.20	8.80	9.10	9.50	9.30	9.40	8.40				
03	9.30	9.30	9.60	8.30	8.90	6.80		9.10	8.40	9.00	8.70	9.20	9.20
04	9.10	8.70	9.10	8.70	8.70	8.60		9.20	8.80	9.00			
05	8.80		8.30	8.40	8.30	8.20	8.50	9.10					
06	9.10	9.40	8.60	8.30	8.50	7.80	9.20	9.30	9.10	8.80	8.70	8.80	9.10
07	9.00		8.60	8.30	8.90	8.70	9.10	9.10	8.70	8.80	8.50		
08	9.00	8.90	8.50	7.80	8.40								
09	8.60	8.70	8.20	7.90	8.60	8.70	9.00	8.70	7.60	8.50	8.80		
10	8.50	8.90	8.60	7.70	8.60	8.50	8.70	8.60	8.30	8.50	9.00		
11	8.50	8.30	8.20	8.10	8.80	8.20	8.60	8.20		8.00			
12	9.50	9.50		8.80	9.10	9.00	9.30	9.40	9.50	9.10	9.20		
13	9.00	8.90	9.10	8.10	8.30	8.70	9.60	8.70	9.00	9.40	9.00		
14	8.70	8.20	8.30	8.90	8.90	8.70	9.00	9.00	8.60				
15	9.10	8.60	8.60	8.20	8.90	8.70	8.80	8.90	9.00	7.70	8.10		
16	8.60	8.00	8.40	8.30	8.40	8.60	8.90	8.40	8.50	8.30	8.10		
17		9.60	8.70										
18	9.30	8.70	9.10	9.30	9.10	8.70	9.20	8.80	9.00	8.70	9.20		
19	9.10	8.80	8.70	9.20	8.80	9.30	8.90	9.30	9.00		8.80		
20	8.50	8.00	8.30	8.70	8.30	8.50	8.30	9.00	6.80	8.30	8.30	8.80	
21	8.90		8.40	8.80	8.80	8.70	8.80	8.80	9.20	8.10	8.80	9.00	
Summary:	Calcium, mg/dL												
Average	8.96	8.83	8.67	8.46	8.71	8.56	8.96	8.94	8.65	8.57	8.70	9.00	9.17
Std Dev	0.31	0.49	0.38	0.44	0.27	0.57	0.33	0.33	0.65	0.46	0.36	0.17	0.06
Max	9.50	9.60	9.60	9.30	9.10	9.50	9.60	9.40	9.50	9.40	9.20	9.20	9.20
Min	8.50	8.00	8.20	7.70	8.30	6.80	8.30	8.20	6.80	7.70	8.10	8.80	9.10

Blank = Not Obtained



Figure 32: SD &amp; Range Charts for Calcium, mg/dL



Units: mg/dL

Table 10f  
Cholesterol

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	200	229	210	198	192	201	210	192	207	188	185	225	184
02		186	167	165	169	177	170	150	118				
03	207	187	225	171	168	175	207	203	167	175	137	146	126
04	191	154	164	179	173	173		171	160				
05	101		92	97	97	101	105	90					
06	191	182	175	172	188	172	201	196	182	177	163	155	176
07	364	308	297	288	326	424	484	440	381	349	171		
08	192	191	186	195	194								
09	202	188	189	200	204	187	214	189	154	182	209		
10	179	164	166	153	158	171	172	171	163	163	171		
11	217	188	186	170	191	158	207	178	192				
12	242	231		224	222	225	232	225	234	206	201		
13	177	183	177	167	162	159	179	160	165	182	166		
14	214	193	185	212	220	206	214	218	220				
15	206	173	184	197	202	213	193	200	201	192	225		
16	173	172	175	175	156	161	166	172	180	157	164		
17													
18	206	173	184	197	202	213	193	200	201	192	225		
19	217	199	196	219	207	201	199	195	222	217	206		
20	118	117	118	114	132	121	141	138	127	109	105	125	
21	184		197	199	198	189	217	199	209	183	185	186	
Summary:	Cholesterol, mg/dL												
Average	199	190	183	185	188	191	206	194	194	191	180	167	162
Std Dev	52	39	40	40	44	64	76	67	57	52	33	39	31
Max	364	308	297	288	326	424	484	440	381	349	225	225	184
Min	101	117	92	97	97	101	105	90	118	109	105	125	126

Figure 33: SD & Range Charts for Cholesterol, mg/dL

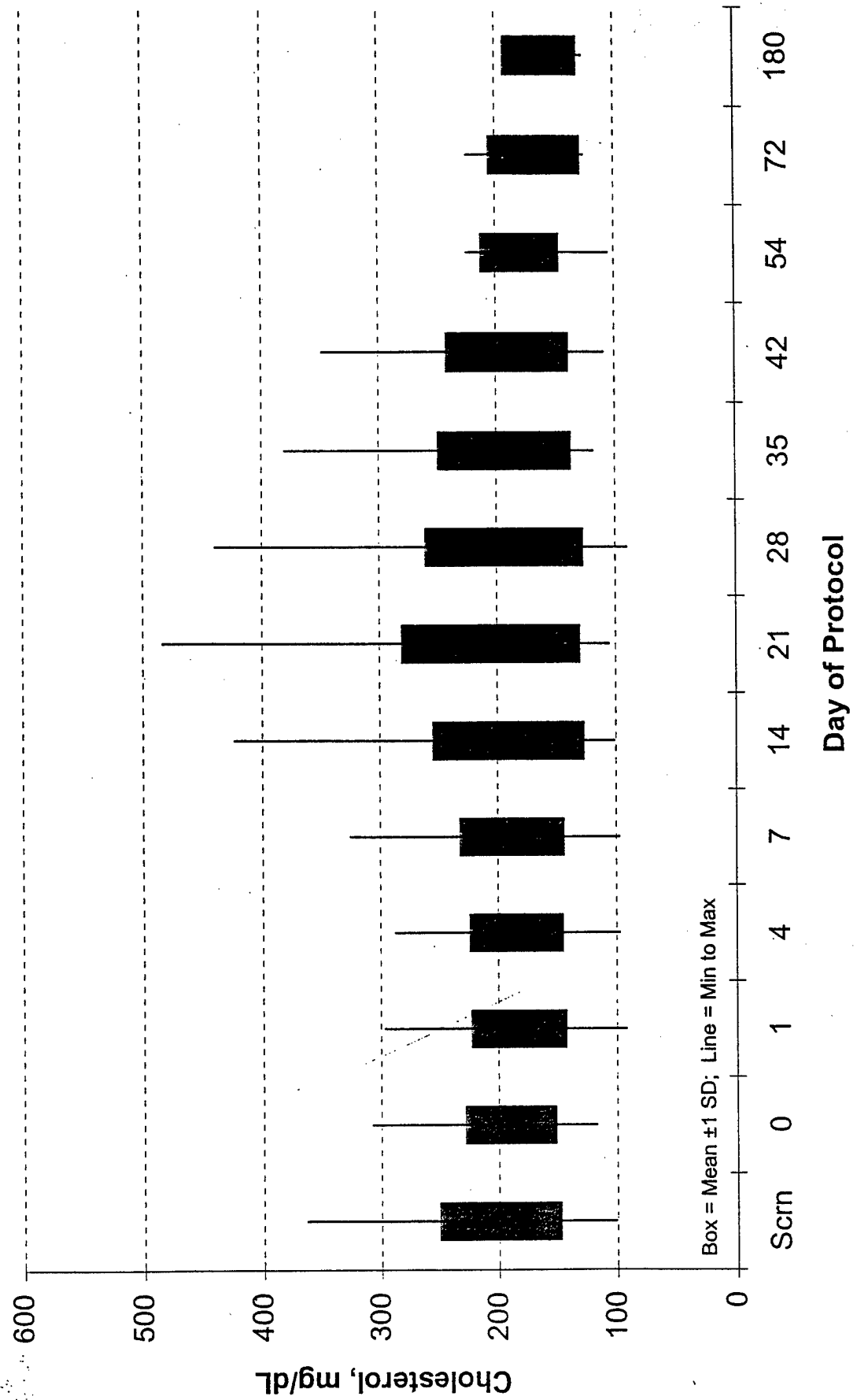


Table 10g  
HDL

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01		57	47	41	32		42	50	54	47	39		38
02		40	40	38	36		40	42	36				
03		66	79	54			52	72	71	47	53	61	50
04	50			55	60			41	44				
05			39	44	44	43	47	49					
06		38	38	37	85	32	33	36		32	36	35	29
07	48		47	46	54		55		43	48	50		
08		44	46			54							
09		42	48	42	40		41	48	41	45	52		
10		47	56	45	46	51	53	59	49	43	57		
11	55	57	59		37	48	49	55					
12		65		55	52	52	38	56	64	56	54		
13			54	44	51	41	51	48	50				
14		60	63	58	73	72	83	92	86				
15		64	61	63	64	66	62	74	61	82	89		
16		58	61	58	60	57	61	66	66	71	60		
17		39											
18		64	61	63	64	66	62		61	83	89		
19		64	61	63	64	66	62	74	61	82	89		
20		44	47	38	36	38	49	46	55	45	46		
21	63		59	40	41	47	41	50	62	55	59		
Summary: HDL													
Average	54	53	54	49	52	52	51	56	57	57	59	48	39
Std Dev	07	11	11	09	15	12	12	15	13	17	18	18	11
Max	63	66	79	63	85	72	83	92	86	83	89	61	50
Min	48	38	38	37	32	32	33	36	36	32	36	35	29

Figure 34: SD & Range Charts for HDL

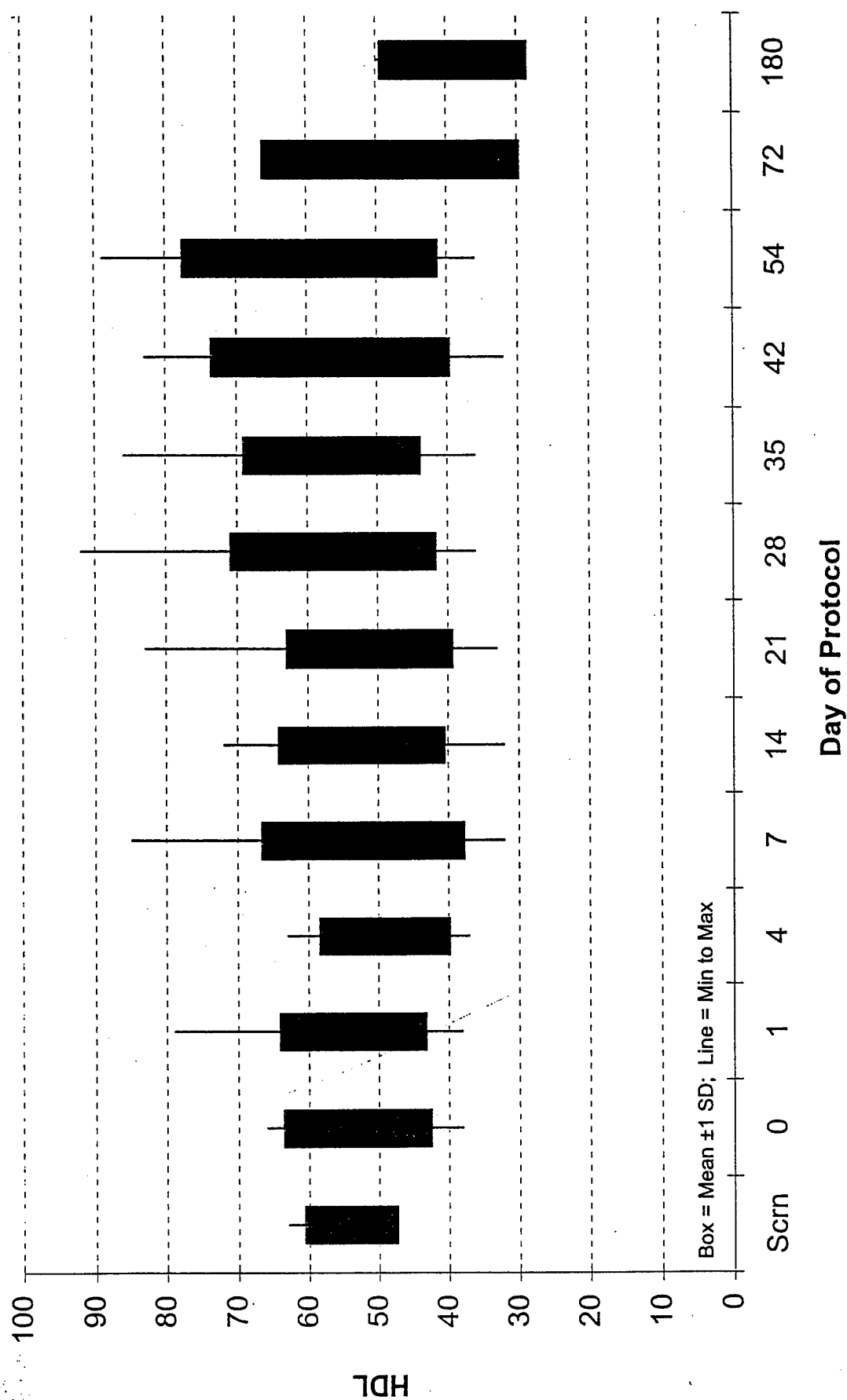
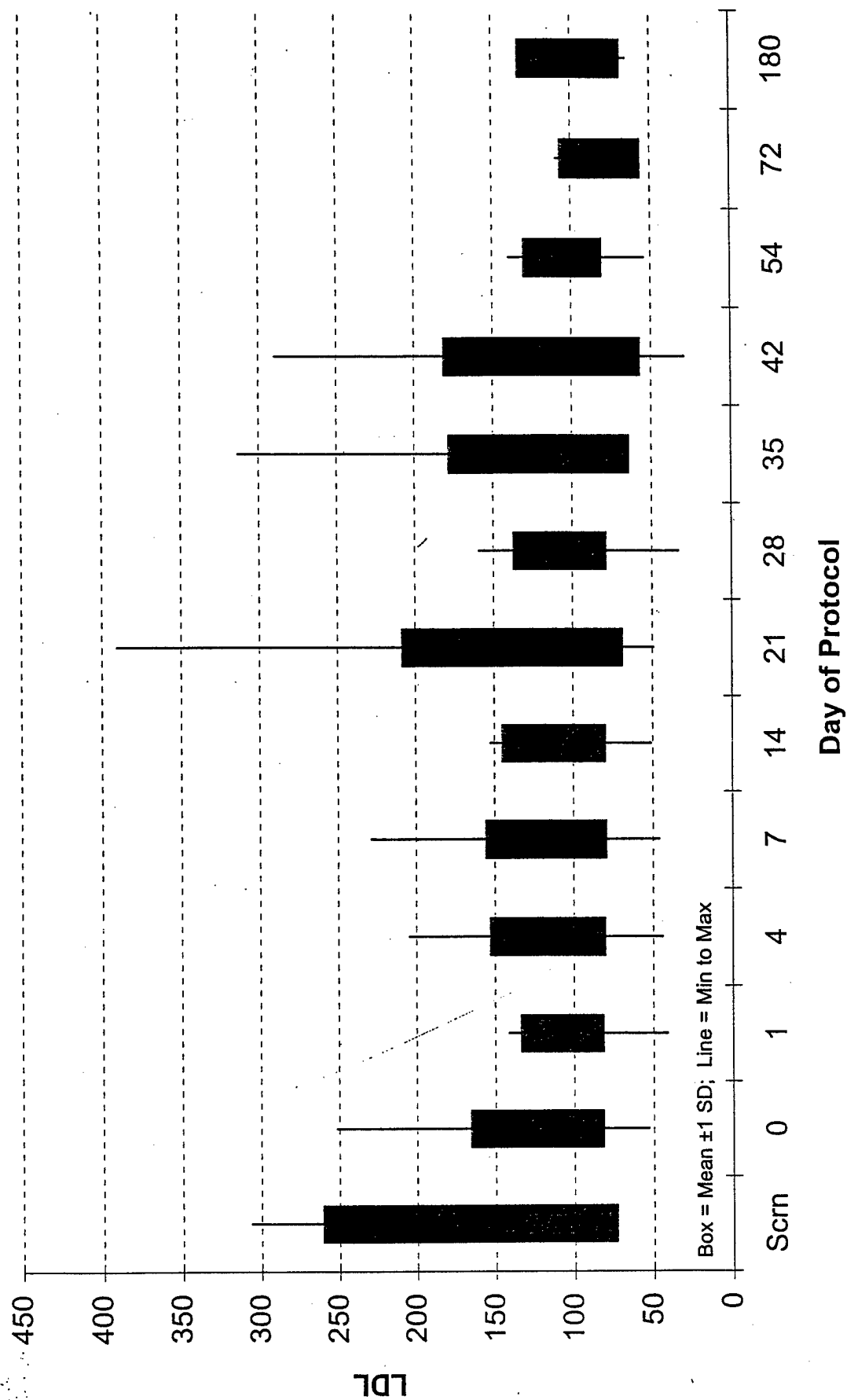


Table 10h  
LDL

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01		150	142	126	121		147	130	132	128	119		111
02		124	114	105	114		111	80	66				
03		111	135	106			148	116	88	116	73	75	65
04	119			95	102			122	107				
05			41	44	46		49	33					
06		123	117	122	83	126	147	146		29	118	110	128
07	307	252		205	229		391		314	290	86		
08		131	122		129								
09		130	123	140	143		157	127	94	122	138		
10		102	98	97	101	99	104	99	98	94	102		
11	133	118	118		117	57	127	109					
12		154		139	150	153	181	160	155	136	122		
13			106	103	98	101	103	93	102				
14		122	114	145	134	125	122	113	125				
15		83	102	120	118	134	123	91	102	87	117		
16		95	103	102	83	92	85	95	101	78	92		
17		150											
18		83	102	120	118	134	123	91	102	87	117		
19		125	127	153	141	139	112	132	151	145	140		
20		53	49	48	67	51	105	79	70		54	60	
21	109		119	133	143	140	162	133	134	118	97		
Summary:	LDL												
Average	167	124	108	117	118	113	139	108	121	119	106	82	101
Std Dev	94	42	26	37	39	33	70	29	57	62	25	26	33
Max	307	252	142	205	229	153	391	160	314	290	140	110	128
Min	109	53	41	44	46	51	49	33	66	29	54	60	65

Figure 35: SD &amp; Range Charts for LDL



Units: mg/dL

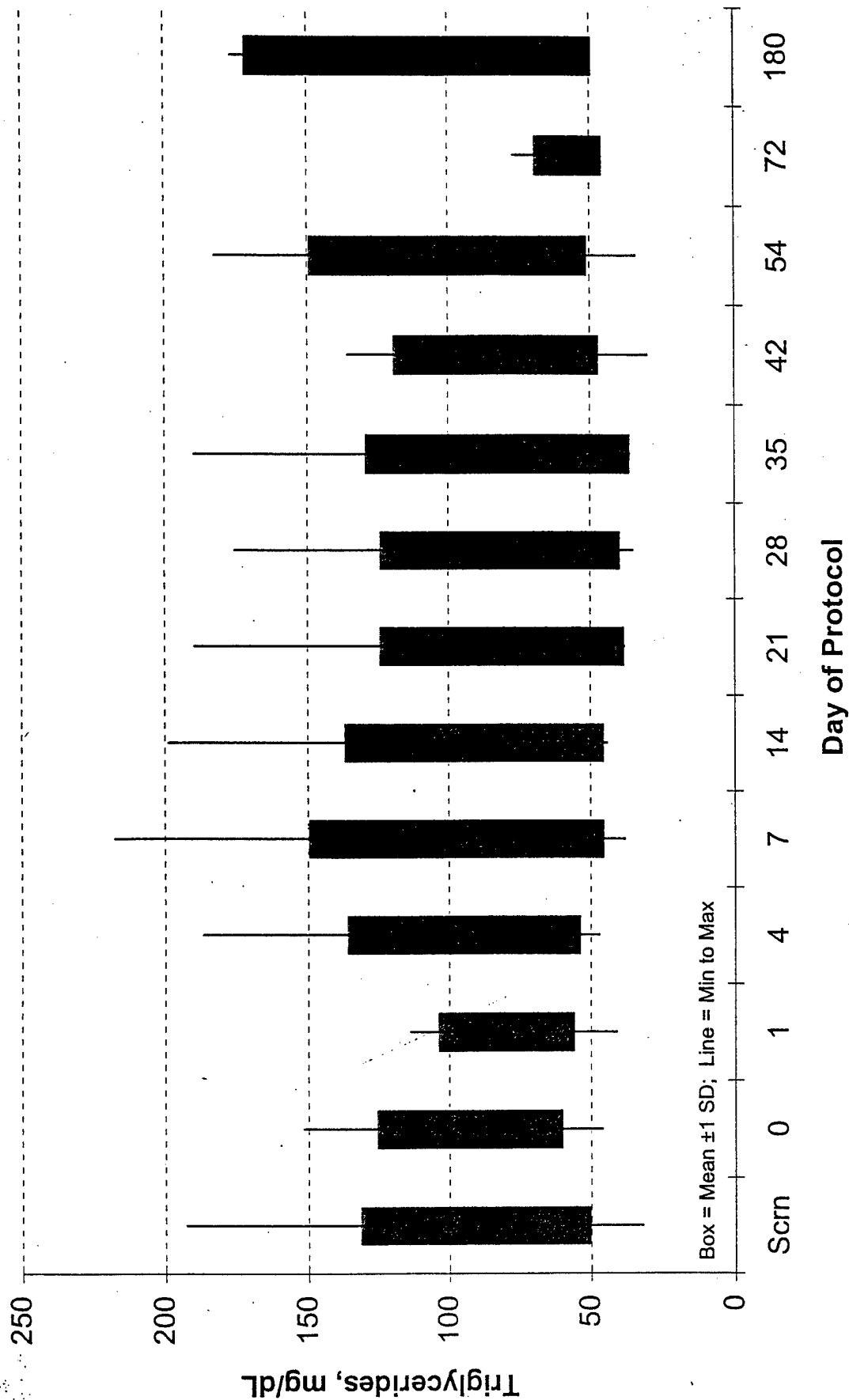
Table 101  
Triglycerides

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	91	110	107	155	197	167	107	64	108	68	136	77	177
02		109	69	113	96	113	95	143	82				
03	65	50	57	55	56	79	38	75	41	64	57	53	56
04	114	125	50	146	56	165		42	46				
05	66		60	47	38	44	46	42					
06	59	106	100	67	101	70	100	70	57	83	46	50	99
07	45	47	41	187	218	199	190	35	124	55	179		
08	62	83	90	59	57								
09	55	80	94	91	105	84	81	73	48	76	99		
10	94	78	64	59	57	108	78	69	84	134	60		
11	145	118	96	123	187								
12	95	60		101	103	65	49	77	74	127			
13	193	88	87	104	69	86	128	95	69	61	183		
14	126	56	41	48	65	45	46	67	46				
15	102	134	108	73	102	65	44	176	190	118	97		
16	73	95	58	78	69	62	104	57	66	42	63		
17													
18	102	134	108	73	102	65	44	176	190	118	97		
19	147	152	114	140	152	122	139	89	81	136	104		
20	32	46	78	47	47	48	47	41	36	30	34	48	
21	62		95	132	73	55	47	84	66	54	149	60	
Summary:	Triglycerides, mg/dL												
Average	91	93	80	95	98	91	81	82	83	83	100	58	111
Std Dev	41	33	24	41	52	46	43	42	47	36	49	12	61
Max	193	152	114	187	218	199	190	176	190	136	183	77	177
Min	32	46	41	47	38	44	38	35	36	30	34	48	56



Figure 36: SD & Range Charts for Triglycerides, mg/dL



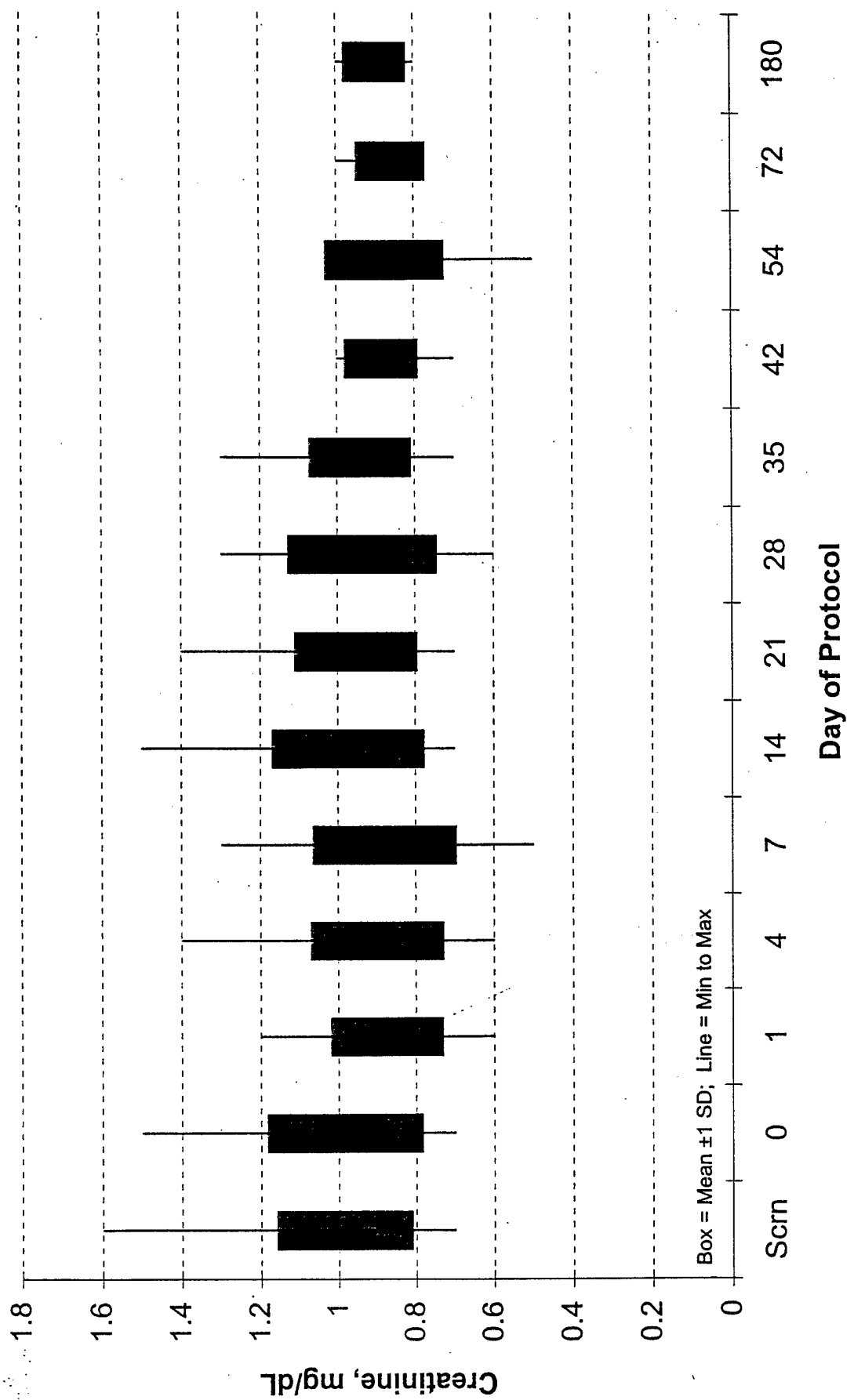
Units: mg/dL

Table 10j  
Creatinine

Blank - Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	1.00	0.90	0.70	0.80	0.90	1.10	0.90	0.80	0.90	0.90	0.80	0.80	1.00
02	1.60	1.40	1.20	1.40	1.30	1.50	1.40	1.30	1.30				
03	0.80	0.80	1.00	0.80	0.70	0.80		0.80	0.70	0.80	0.80	0.80	0.80
04	1.10	1.00	0.80	0.70	0.70	0.70		0.80	0.80				
05	1.00		1.00	0.90	1.10	1.30	1.10	1.20					
06	0.90	0.90	0.80	0.80	0.80	0.70	0.90	0.80	0.90	0.80	0.80	0.80	0.90
07	0.80		0.60	0.60	0.50	0.80	0.80	0.60	0.80	1.00	0.70		
08	1.00	0.90	0.80	0.90	0.70								
09	1.00	0.90	0.80	0.90	0.90	0.90	0.90	1.00	0.90	0.90	0.90		
10	0.90	0.90	0.70	0.90	0.70	1.00	0.80	0.80	0.90	0.90	1.00		
11	0.70	0.70	0.80	0.70	0.80	0.80	0.70	0.60		0.70			
12	1.00	1.20		1.10	1.00	1.00	1.10	1.10	1.00	1.00	1.00		
13	0.90	1.00	0.90	0.80	0.90	1.00	1.00	0.90	0.90	1.00	1.00		
14	1.00	1.00	0.80	0.90	1.10	1.10	1.00	1.00	0.90				
15	1.00	0.90	1.00	1.00	1.10	1.00	0.90	1.10	1.00	0.90	1.00		0.90
16	1.00	1.00	0.90	0.90	0.90	1.10	0.90	1.00	0.90	0.90	1.00		
17		1.50	1.10										
18	1.00	1.00	1.00	1.10	0.90	0.90	1.00	1.00	1.10	1.00			
19	0.90	0.80	0.90	0.90	0.80	1.00	1.00	0.90	1.00		0.50		
20	1.00	0.90	0.90	0.90	0.80	0.90	0.80	0.90	1.00	0.80	0.90	0.90	
21	1.10		0.80	1.00	1.00	0.90	1.00	1.20	1.00	0.80	1.00	1.00	
Summary:	Creatinine, mg/dL												
Average	0.99	0.98	0.88	0.90	0.88	0.97	0.95	0.94	0.94	0.89	0.88	0.86	0.90
Std Dev	0.18	0.20	0.14	0.17	0.19	0.20	0.16	0.19	0.13	0.09	0.15	0.09	0.08
Max	1.60	1.50	1.20	1.40	1.30	1.50	1.40	1.30	1.30	1.00	1.00	1.00	1.00
Min	0.70	0.70	0.60	0.60	0.50	0.70	0.70	0.60	0.70	0.70	0.50	0.80	0.80

Figure 37: SD & Range Charts for Creatinine, mg/dL



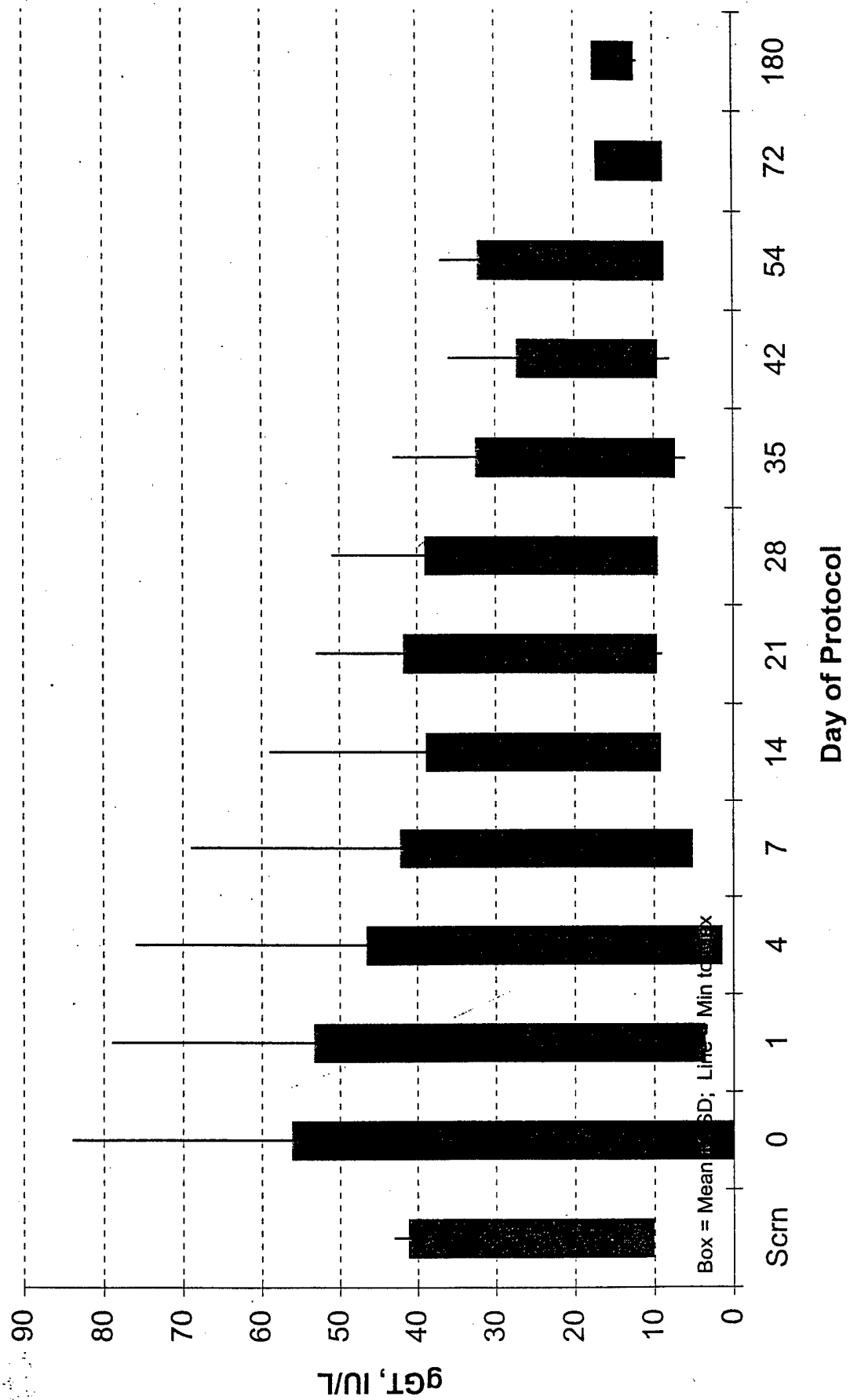
Blank = Not Obtained

Table 10k  
gGT

Units: IU/L

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01													16
02													
03													17
04													
05													
06									14	9	11	10	12
07						21	21	19	6		14		
08													
09						10	13	12	10		10		
10						24	20	24		21			
11						27	44	37		22	35		
12				28	26	28	28	28	25	23	37		
13	13	13	9	10	11	12	13	12	10		11		
14	43	84	79	76	69	59	53	47	43				
15	21	19	17	17	15	11	15		20	16	18		
16		31	30	29	26	35	48	51	42	36	35		
17			60										
18			26			43	45		30	26	37		
19		7	11	11	12	10	9	11	13	10	12		
20		5	8	6	9	10	10	12	9	8	9		
21			16	15	16	22	15	14	17	13	16	16	
Summary:	gGT, IU/L												
Average	26	27	28	24	24	24	26	24	20	18	20	13	15
Std Dev	16	30	25	23	19	15	16	15	13	09	12	04	03
Max	43	84	79	76	69	59	53	51	43	36	37	16	17
Min	13	05	08	06	09	10	09	11	06	08	09	10	12

Figure 38: SD &amp; Range Charts for gGT, IU/L



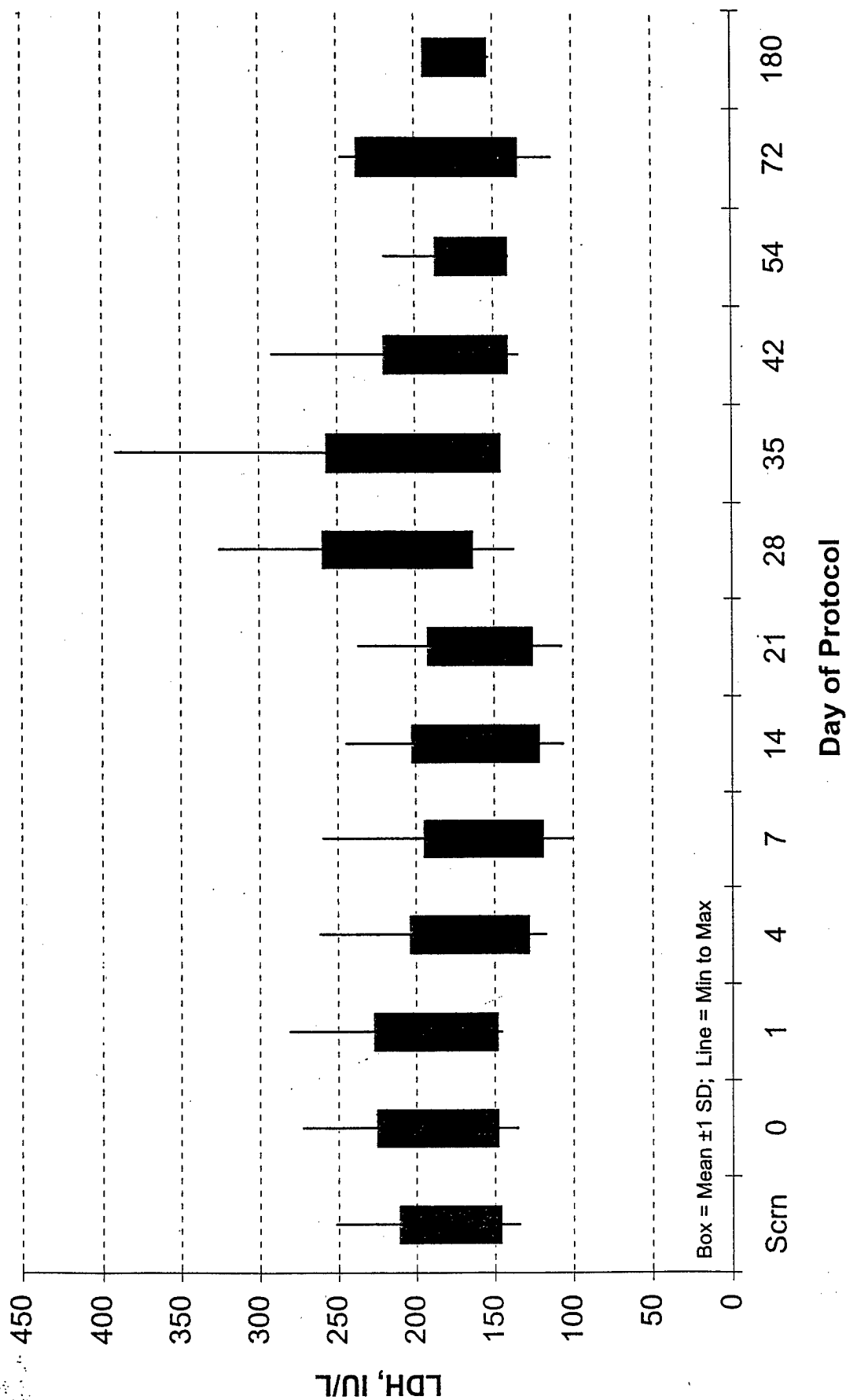
Units: IU/L

Table 10L  
LDH

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	158	158	152	138	130	153	161	163	161	160	140	113	152
02	165	180	208	155	140	175	198	196	195				
03	185	176	222	219	170	231		194	165	292	161	220	191
04	183	176	200	177	157	146		268	194	218			
05	153		189	126	126	120	130	155					
06	134	163	155	152	128	126	133	195	147	170	151	177	161
07	243		252	186	260	181	237	262	392	226	220		
08	179	158	196	181	171								
09	138	135	192	185	191	156	196	261	211	160	149		
10	171	169	154	196	177	156	196	261	211	160	149		
11	191	178	168		152	132	170	204		147			
12	208	259		213	218	208	164	184	185	181	157		
13	156	168	186	117	170	106	120	137	169	176	148		
14	160	189	258	131	126	129	155	202	257				
15	188	166	145	127	166	245	128		175	147	145		192
16	153	157	152	130	119	127	146	194	197	165	149		
17		231	164										
18	230	173	159	147	101	123	107	233	170	134	178		
19	161	247	161	144	118	148	154	162	170		164		
20	252	273	281	262	184	207	171	326	222	195	188	248	
21	163		154	168	134	209	136	209	201	175	196	171	
Summary:	LDH, IU/L												
Average	179	186	187	166	157	162	159	211	201	180	164	186	174
Std Dev	33	39	40	38	38	41	34	48	56	40	23	52	21
Max	252	273	281	262	260	245	237	326	392	292	220	248	192
Min	134	135	145	117	101	106	107	137	147	134	140	113	152

Figure 39: SD & Range Charts for LDH, IU/L



Units: mg/dL

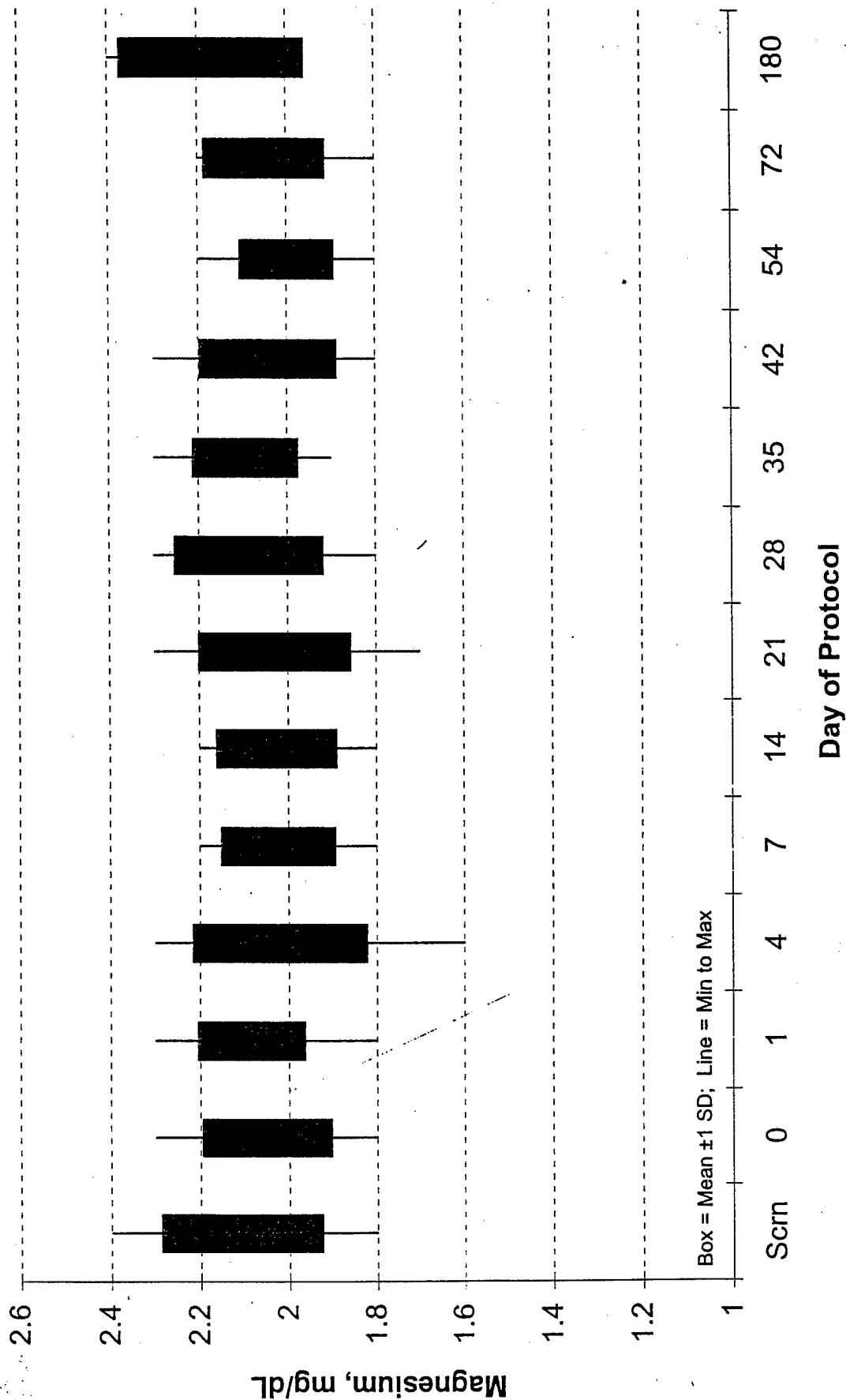
Table 10m  
Magnesium

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	2.0	2.0	2.1	2.2		1.9	2.1	2.0	2.0	2.2	2.1	2.1	2.1
02	2.3	1.9		1.6		1.8	2.0	1.8	2.1				
03	2.0	1.9	2.0	1.7		1.9		2.2	1.9	2.1	2.0	2.0	2.4
04	2.3		2.1	1.9	1.9	1.9			2.0	2.2			
05	1.9		1.9		1.9	1.9	1.9						
06	1.9	1.9	2.0	2.0	2.1	1.9	2.0	2.0	1.9	2.1	2.1	2.1	2.0
07	2.2	2.1	2.3		2.1	2.2	2.3	2.3	2.2		2.0		
08	2.1	2.0	2.2		2.2								
09	2.1	2.0	2.1		2.1	2.1	2.2		2.2	2.3	1.9		
10	1.9	1.8	1.8	1.8	1.8	2.2	1.7	1.8	2.0	2.0		1.8	
11	2.4	2.0	2.0	2.3	2.2	2.2	2.1		2.0				
12	2.2	2.2		2.0	2.1	2.1	2.1	2.0	2.1	2.0	1.9		
13	2.1	2.2	2.1	2.1	2.1	2.1	2.1	2.2	2.1	2.2	2.0		
14	2.4	2.2	2.2	2.3	2.2	2.2	2.2	2.3	2.3				
15		2.0	2.1	2.1	1.9	2.1	1.8	2.1	2.1	1.8	1.9		
16	2.2	2.1	2.1	2.0	1.9	2.0	2.0	2.2	2.2	1.9	2.0		
17		2.3	2.2										
18		1.9	2.0	2.0	1.9	1.9	2.1	2.1	2.1	1.9	2.1		
19		2.3	2.2	2.2	2.1	2.2	2.2	2.3	2.3	2.1	2.2		
20	1.8	2.1	2.2	2.1	1.9	1.9	1.7	2.1		1.8	1.8	2.1	
21	2.0		2.0	2.0	2.0	2.0	2.0	1.9	2.1	2.0	2.0	2.2	
Summary:	Magnesium, mg/dL												
Average	2.1	2.1	2.1	2.0	2.0	2.0	2.0	2.1	2.1	2.0	2.0	2.1	2.2
Std Dev	0.2	0.1	0.1	0.2	0.1	0.1	0.2	0.2	0.1	0.2	0.1	0.1	0.2
Max	2.4	2.3	2.3	2.3	2.2	2.2	2.3	2.3	2.3	2.3	2.2	2.2	2.4
Min	1.8	1.8	1.8	1.6	1.8	1.8	1.7	1.8	1.9	1.8	1.8	1.8	2.0



Figure 40: SD & Range Charts for Magnesium, mg/dL



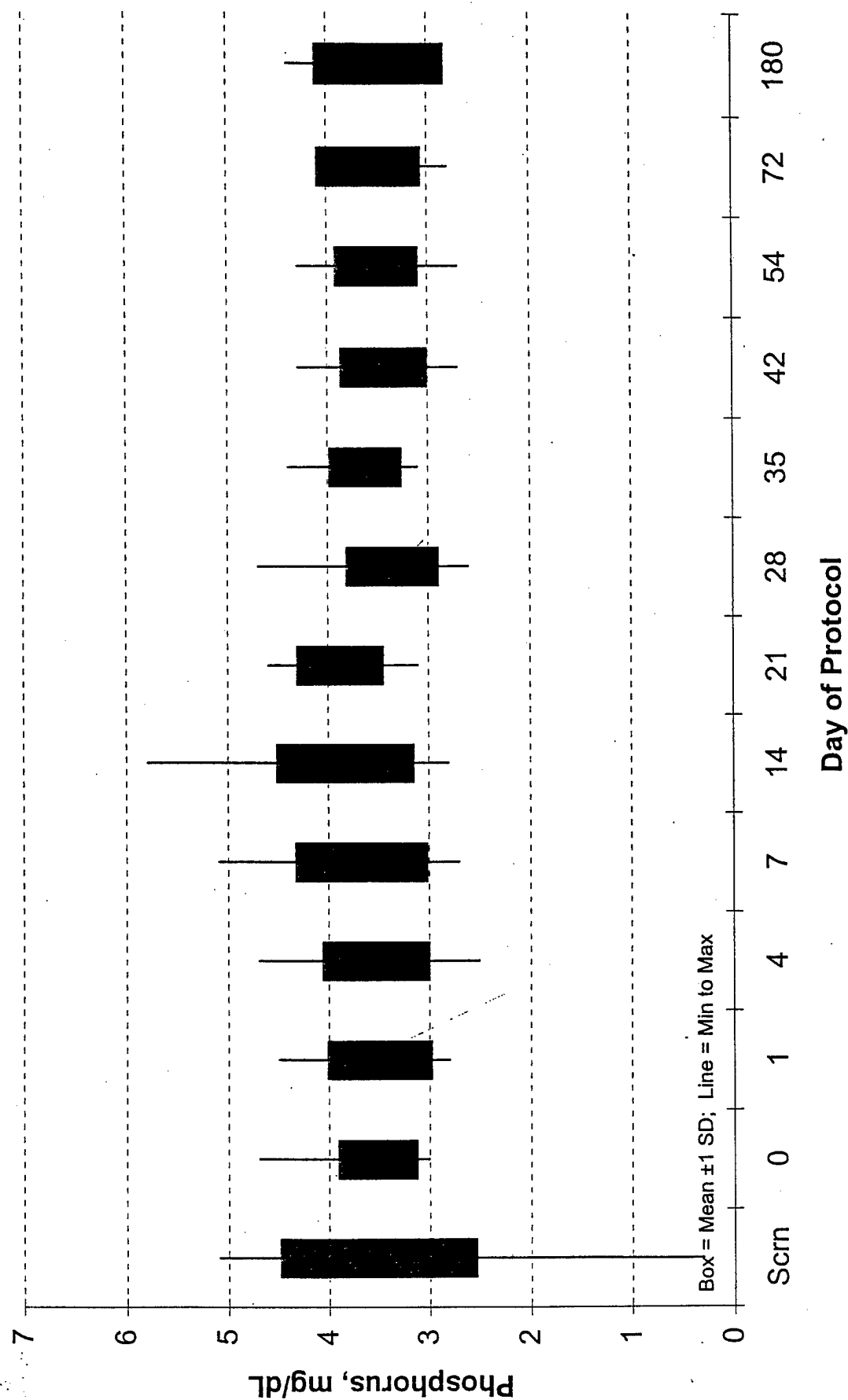
Units: mg/dL

Table 10n  
Phosphorus

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	4.0	3.3	2.9	4.2	4.7	3.7	3.6	3.4	4.0	4.3	3.8	4.0	3.3
02	4.7	3.9	4.0	3.9	4.1	5.8	4.6	4.7	4.0				
03	2.6	3.3	2.9	3.0	3.1	3.2	3.5	3.6	3.4	3.4	2.7	2.8	2.9
04	5.1	4.7	3.2	3.5	3.4	4.1		3.0	3.8				
05	3.1		2.8	2.5	3.8	3.4	4.1	2.9					
06	3.9	3.9	3.2	3.5	3.6	3.7	3.9	3.5	3.6	3.3	3.1	3.6	3.3
07	3.0		3.1	3.1	3.3	3.7	4.4	3.5	3.1				
08	3.5	3.4	4.3	4.3	5.1	4.4							
09	4.1	3.5	4.3	3.6	4.3	3.4	3.7	3.1	3.4	3.2	3.8		
10	3.3	3.3	3.5	3.3	3.3	3.0	3.1	3.2	3.3	3.2	3.6		
11	2.9	3.0	3.1	2.9	2.7	2.8	3.5	2.6		2.7			
12	3.0	3.2		3.0	3.7	3.4	3.6	3.9	3.7	3.3	3.5		
13	3.7	3.4	3.9	3.7	3.4	3.9	4.4	3.7	3.3	4.0	4.3		
14	4.5	4.0	3.5	3.6	3.5	4.1		3.4	3.6				
15	3.6	3.4	4.5	4.7	4.7	4.7	3.7	3.4	3.8	3.8	3.1		4.4
16	0.3	3.3	3.1	3.2	3.0	3.0	3.2	2.9	3.2	3.2	3.5		
17		3.4	4.1										
18	3.6	3.7	3.0	3.4	2.8	3.8	4.1	3.0	4.1	3.2	3.8		
19	3.8	3.4	3.5	3.8	3.2	4.0	4.2	3.6	3.7		3.1		
20	3.6	3.2	3.4	3.3	3.5	4.1	4.0	3.0	3.2	3.2	3.6	3.4	
21	3.9		3.6	4.1	4.2	4.4	4.3	3.4	4.4	3.9	3.7	4.1	
Summary:	Phosphorus, mg/dL												
Average	3.5	3.5	3.5	3.5	3.7	3.8	3.9	3.4	3.6	3.4	3.5	3.6	3.5
Std Dev	1.0	0.4	0.5	0.5	0.7	0.7	0.4	0.5	0.4	0.4	0.4	0.5	0.6
Max	5.1	4.7	4.5	4.7	5.1	5.8	4.6	4.7	4.4	4.3	4.3	4.1	4.4
Min	0.3	3.0	2.8	2.5	2.7	2.8	3.1	2.6	3.1	2.7	2.7	2.8	2.9

Figure 41: SD &amp; Range Charts for Phosphorus, mg/dL



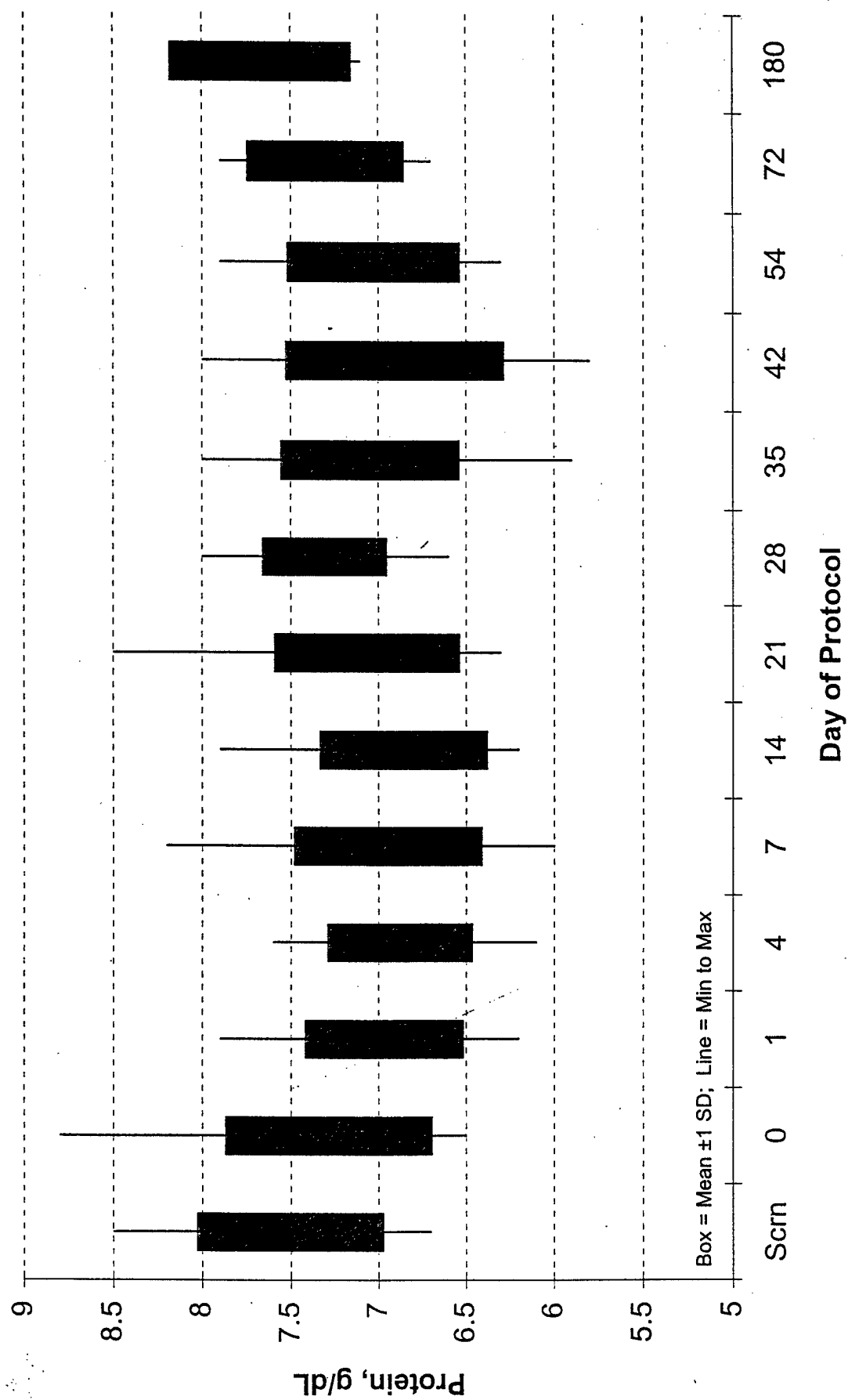
g/dL

Table 10o  
Protein

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	8.50	8.80	7.90	7.60	7.40	7.90	8.50	7.30	7.10	8.00	7.70	7.90	8.10
02	7.30	7.40	7.00	6.80	6.90	7.60	7.20	7.30	6.90				
03	7.20	6.60	7.60	6.10	6.00	6.40		7.40	6.10	6.50	6.60	6.70	7.10
04	7.30	6.60	7.20	6.90	6.90	6.60		7.60	7.20	7.60			
05	6.70		6.40	6.10	6.10	6.20	6.50	7.60					
06	7.70	7.40	7.20	6.90	7.00	6.60	7.60	7.70	8.00	7.40	7.40	7.30	7.80
07	7.80		6.90	6.70	7.70	7.30	7.50	7.60	7.60	7.00	7.10		
08	8.20	7.50	7.40	7.10	7.50								
09	7.10	6.50	6.40	6.50	6.80	6.60	7.00	6.70	5.90	6.70	6.80		
10	7.50	7.20	7.30	7.00	7.00	7.40	6.60	7.40	7.20	6.80	7.60		
11	7.90	7.80	7.50		8.20	6.70	7.40	7.20		6.90			
12	8.50	7.50		7.40	7.20	7.60	7.50	7.50	7.70	7.20	7.20		
13	7.50	7.50	6.70	6.30	6.70	6.60	7.10	6.90	7.00	7.90	7.00		
14	7.20			7.20	7.50	7.10	7.10	7.10	6.90				
15	8.20	7.20	6.50	6.90	6.70	6.50	6.80		7.40	5.80	6.30		
16	7.10	7.00	6.60	6.90	6.50	6.50	6.70	7.00	6.90	6.20	7.00		
17		8.10	7.10										
18	7.20	7.00	6.80	7.00	6.70	6.60	6.70	7.20	7.00	6.60	7.90		
19	6.80	6.70	6.20	6.80	6.30	6.50	6.30	6.60	6.80		6.40		
20	7.10	7.00	6.90	7.50	6.80	6.70	6.70	8.00	7.00	6.30	6.50	7.50	
21	7.20		6.80	7.00	7.00	6.90	6.90	7.40	7.10	6.70	6.90	7.10	
Summary: Protein, g/dL													
Average	7.50	7.28	6.97	6.88	6.95	6.86	7.06	7.31	7.05	6.91	7.03	7.30	7.67
Std Dev	0.53	0.59	0.45	0.42	0.54	0.48	0.53	0.36	0.51	0.62	0.49	0.45	0.51
Max	8.50	8.80	7.90	7.60	8.20	7.90	8.50	8.00	8.00	8.00	7.90	7.90	8.10
Min	6.70	6.50	6.20	6.10	6.00	6.20	6.30	6.60	5.90	5.80	6.30	6.70	7.10

Figure 42: SD &amp; Range Charts for Protein, g/dL



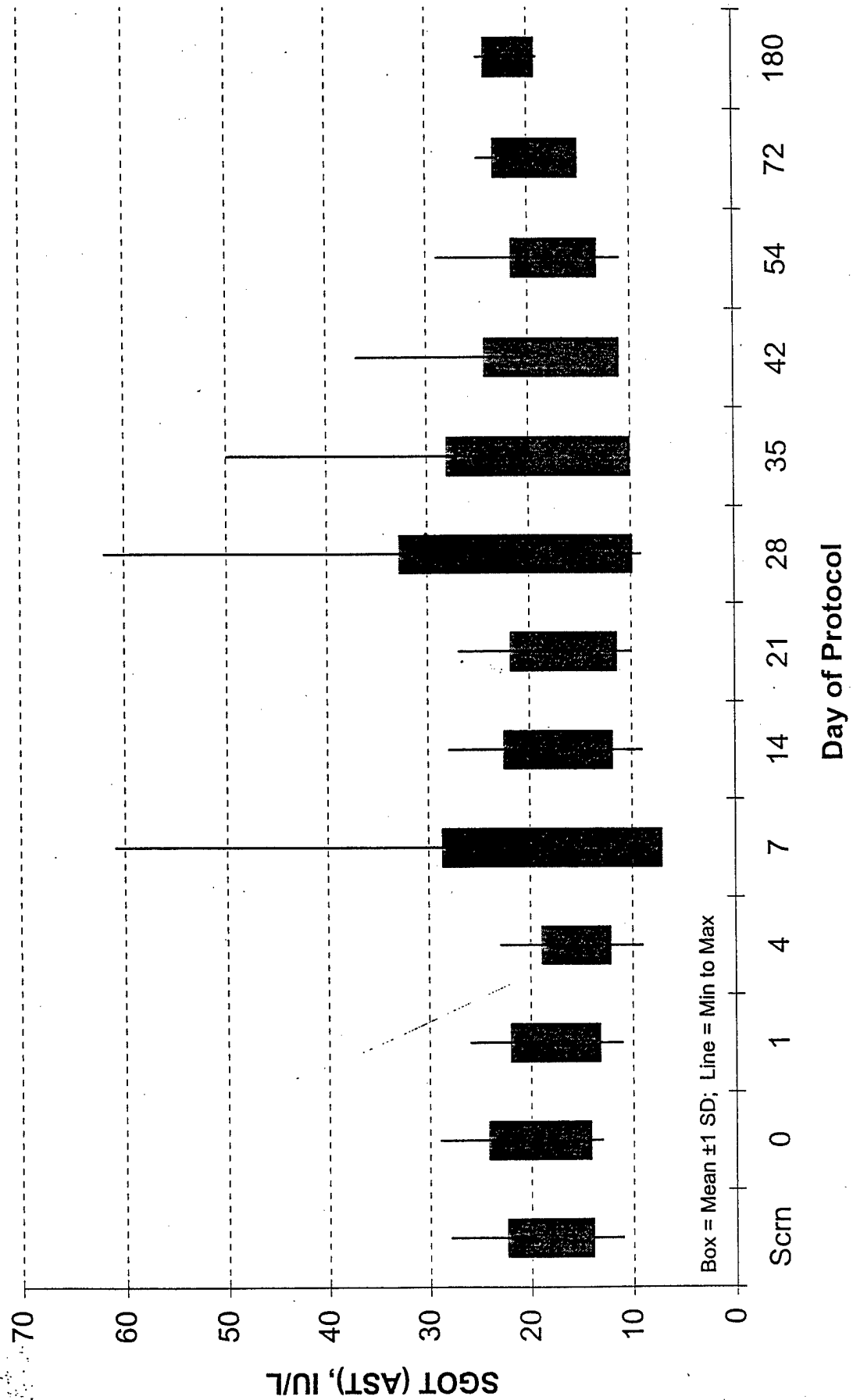
Units: IU/L

Table 10p  
SGOT (AST)

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	18	19	19	15	17	17	19	15	13	14	14	17	22
02	21	29	26	21	18	22	20	17	18				
03	15	18	24	19	14	22		22	16	37	16	25	21
04	18	17	17	15	18	17		17	18	19			
05	11		14	13	13	9	10	14					
06	16	16	15	14	19	16	22	23	19	16	18	15	19
07	20		25	14	61	24	26	28	30	23	21		
08	14	13	11	12	13								
09	20	16	16	17	15	16	13	62	50	12	16		
10	16	17	14	17	15	18	14	18	16	15	18		
11	17	18	15		14	10	16	16		11			
12	25	27		18	20	21	20	18	17	19	15		
13	16	16	17	14	14	11	13	18	17	20	16		
14	18	17	14	13	13	13	12	12	14				
15	18	15	14	13	13	16	11		16	13	11		25
16	26	22	20	23	26	28	27	30	22	23	29		
17		26	23										
18	28	28	22	13	16	24	19	19	13	18	17		
19	15	13	12	9	8	10	10	9	11		15		
20	14	18	16	19	16	14	17	26	16	12	17	17	
21	17		18	16	15	19	14	20	18	13	21	22	
Summary:	SGOT (AST), IU/L												
Average	18	19	18	16	18	17	17	21	19	18	17	19	22
Std Dev	04	05	04	03	11	05	05	11	09	07	04	04	03
Max	28	29	26	23	61	28	27	62	50	37	29	25	25
Min	11	13	11	09	08	09	10	09	11	11	11	15	19

Figure 43: SD & Range Charts for SGOT (AST), IU/L



Units: IU/L

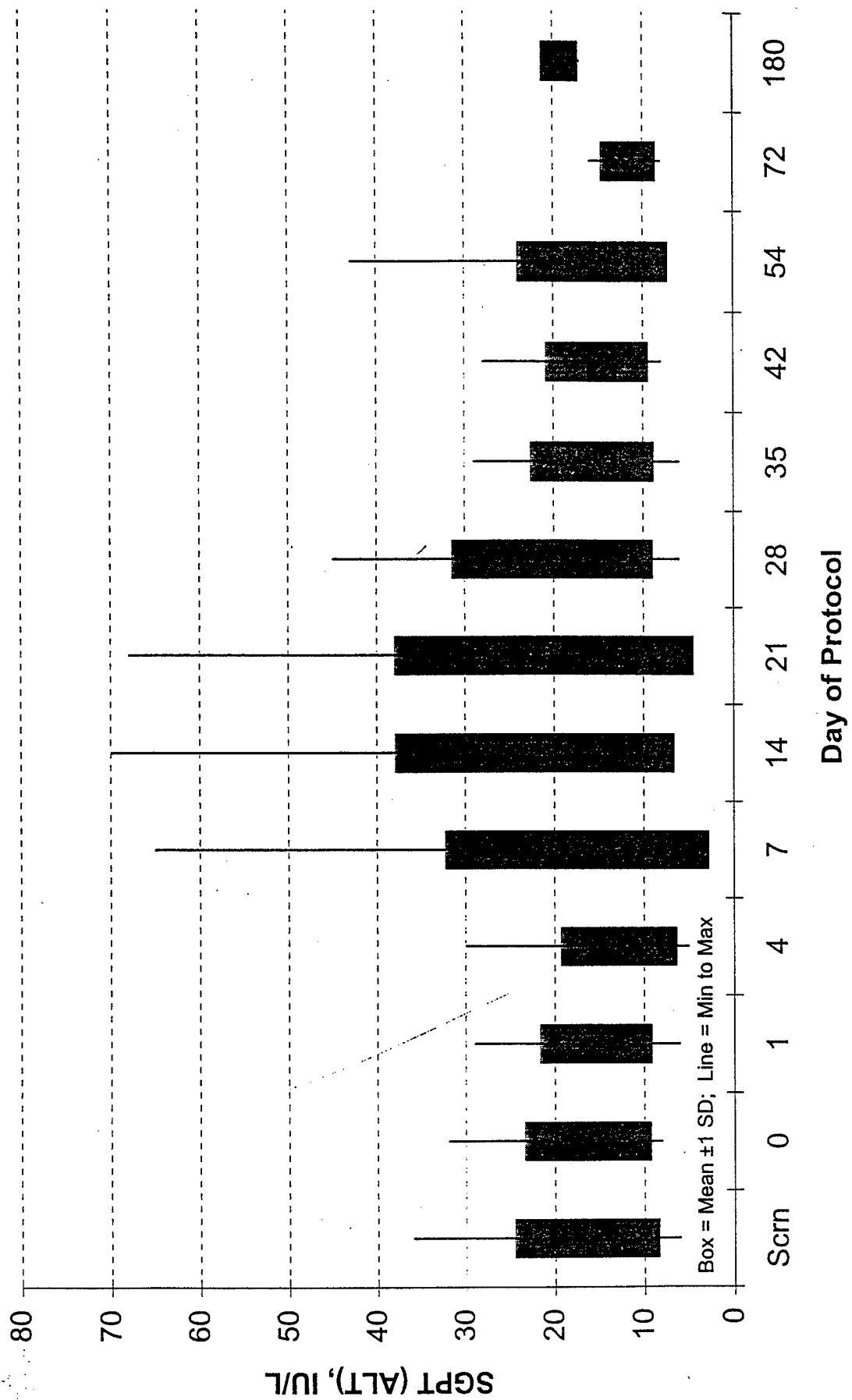
Table 10q  
SGPT (ALT)

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	15	17	16	11	17	19	20	15	9	10	9	11	18
02	24	32	29	27	27	32	26	21	14				
03	11	13	16	13	11	21		13	15	24	15	16	17
04	16	20	21	20	30	34		22	13	14			
05	6		10	9	9	8	6	8					
06	16	15	14	11	18	20	25	29	18	10	15	8	21
07	13		16	12	65	45	55	40	29	20	14		
08	9	8	6	6	6								
09	27	17	15	14	11	11	9	45	28	18	19		
10	9	11	19	7	11	17	15	17	12	14	15		
11	15	11	11		6	9	11	9	15	8			
12	16	13		13	14	20	19	17	9	13	13		
13	6	8	7	5	4	9	6	6	6	10	10		
14	32	20	17	13	15	13	14	16	12				
15	16	13	11	8	11	12	13		23	16	13		21
16	36	27	25	30	46	70	68	36	28	28	43		
17		30	27										
18	22	16	14	11	16	39	31	29	16	19	14		
19	13	13	11	10	11	16	11	14	12		12		
20	11	10	10	10	11	12	15	10	13	10	9	10	
21	16		13	14	12	16	17	17	11	13	18	13	
Summary:	SGPT (ALT), IU/L												
Average	16	16	15	13	18	22	21	20	16	15	16	12	19
Std Dev	08	07	06	06	15	16	17	11	07	06	08	03	02
Max	36	32	29	30	65	70	68	45	29	28	43	16	21
Min	06	08	06	05	04	08	06	06	06	08	09	08	17



Figure 44: SD &amp; Range Charts for SGPT (ALT), IU/L



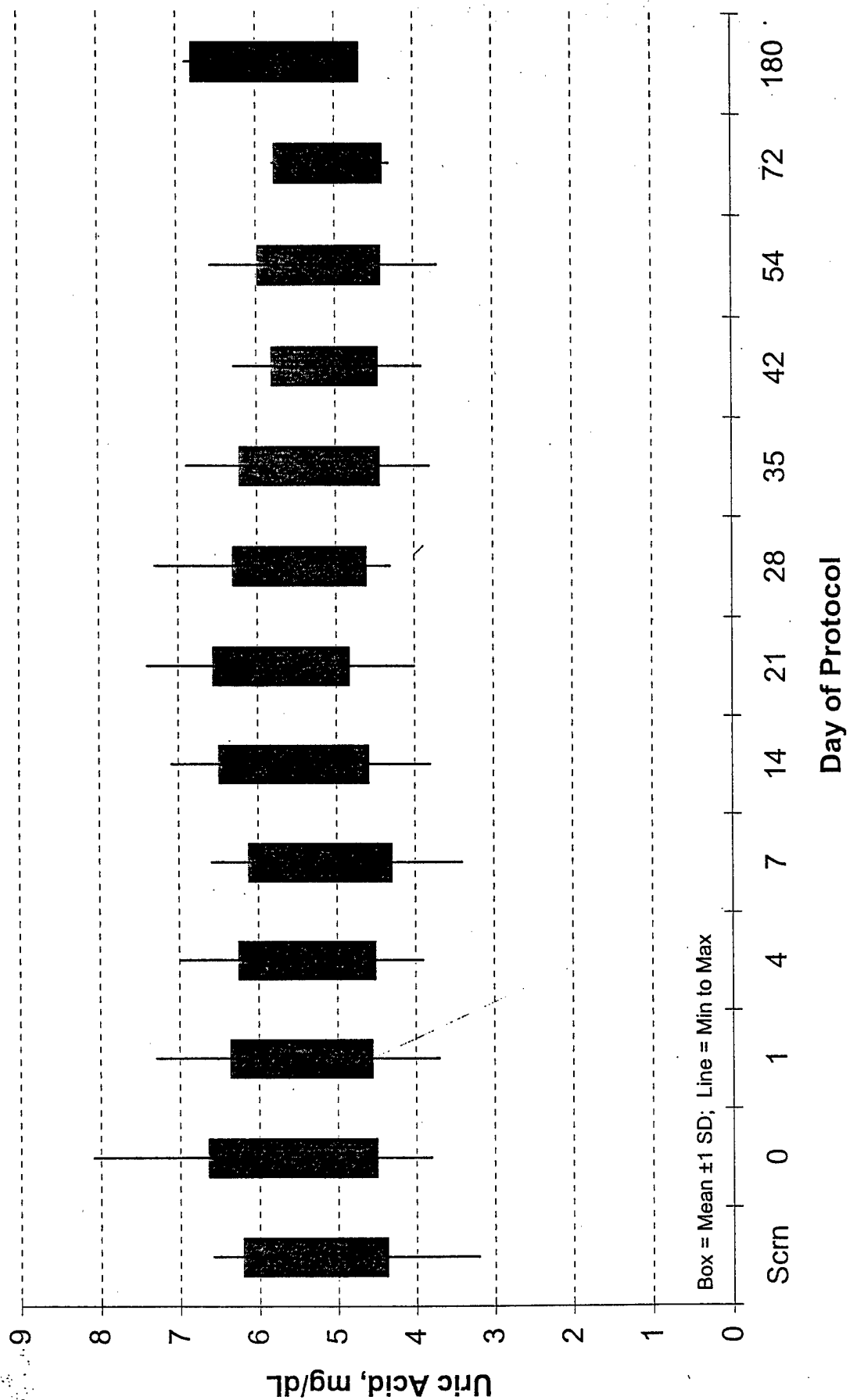
Blank = Not Obtained

Table 10r  
Uric Acid

Units: mg/dL

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	5.6	6.6	6.9	5.8	6.1	7.1	7.4	6.0	6.9	6.3	6.1	5.8	6.9
02	6.3	5.7	5.7	5.5	6.0	5.8	6.3	5.0	4.2				
03	3.2	3.8	5.5	4.4	3.7	3.9		4.8	3.8	4.5	3.7	4.3	4.7
04	5.2	5.1	5.1	5.5	5.2	5.0		5.8	5.8	5.2			
05	5.8		6.4	5.6	5.7	5.6	5.7	5.4					
06	4.8	4.5	4.7	4.0	4.8	4.4	4.6	4.5	4.3	5.2	5.3	4.4	5.0
07	6.3		4.9	4.8	4.8	5.7	5.6	7.3	5.1	6.0	5.8		
08	5.5	5.4	5.4	5.7	5.4								
09	6.1	4.5	4.3	4.8	5.0	5.6	5.4	4.3	5.7	4.8	4.6		
10	3.9	3.8	3.7	4.7	3.9	5.1	4.5	4.3	4.5	4.6	4.1		
11	4.1	6.5	4.5	3.9	3.4	3.8	4.0	4.6		3.9			
12	4.4	6.0		5.2	5.0	5.2	5.2	5.6	5.4	4.8	5.2		
13	4.6	4.8	4.8	4.8	4.1	4.7	5.0	4.9	4.2	4.7	4.8		
14	5.3	6.1	6.0	6.9	6.6	7.1	6.6	6.7	5.7				
15	6.6	6.0	6.4	7.0	6.6	6.6	5.9	5.5	6.1	6.3	5.8		6.4
16	4.8	5.1	4.9	5.5	5.3	5.2	5.6	5.1	4.9	5.1	4.9		
17		8.1	7.3										
18	5.4	6.1	5.6	5.1	5.5	5.8	6.1	6.7	5.8	4.7	4.8		
19	6.6	6.5	6.4	6.9	6.4	6.8	6.5	5.9	6.7		6.6		
20	5.6	5.7	5.6	5.7	5.4	6.1	6.6	6.2	5.7	5.4	5.7	5.6	
21	5.7		5.1	5.9	5.3	5.8	5.9	5.2	5.8	5.5	5.4	5.3	
Summary:	Uric Acid, mg/dL												
Average	5.3	5.6	5.5	5.4	5.2	5.5	5.7	5.5	5.3	5.1	5.2	5.1	5.8
Std Dev	0.9	1.1	0.9	0.9	0.9	1.0	0.9	0.9	0.9	0.7	0.8	0.7	1.1
Max	6.6	8.1	7.3	7.0	6.6	7.1	7.4	7.3	6.9	6.3	6.6	5.8	6.9
Min	3.2	3.8	3.7	3.9	3.4	3.8	4.0	4.3	3.8	3.9	3.7	4.3	4.7

Figure 45: SD & Range Charts for Uric Acid, mg/dL



per LPF

Table 11a  
Urinalysis: Casts

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01													
02													
03													
04													
05													
06													
07													
08													
09													
10													
11													
12													
13													
14													
15													
16													
17													
18													
19													
20													
21													

Table 11b  
Urinalysis: Occult Blood

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	-	-	-	-	-	-	-	-	-	-	-	-	-
02	-	-	-	-	-	-	-	-	-	-	-	-	-
03	4+	-	1+	-	-	-	4+	1+	1+	-	-	4+	4+
04	-	-	-	-	-	-	-	-	-	-	-	-	-
05	-	-	-	-	-	-	-	-	-	-	-	-	-
06	-	-	-	-	-	-	-	-	-	-	-	-	-
07	-	-	-	-	-	-	-	-	-	-	-	-	-
08	-	-	-	-	-	-	-	-	-	-	-	-	-
09	-	-	-	-	-	-	-	-	-	-	-	-	-
10	-	-	1+	-	-	-	-	-	4+	-	-	-	-
11	-	-	-	-	-	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-	+	-	-	-	-
13	-	-	-	-	-	-	-	-	-	-	-	-	-
14	-	-	-	-	-	-	1+	+	+	-	-	-	-
15	-	-	-	-	-	-	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-	-	-	-	-	-
18	-	-	-	-	-	-	-	-	-	-	-	-	-
19	-	-	-	-	-	-	-	-	-	-	-	-	-
20	-	-	-	-	-	-	-	-	-	-	-	-	-
21	-	-	-	-	-	-	-	-	-	-	-	-	-

Table 11c  
Urinalysis: RBC

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
1	0	0	0	0	0	0	0	0	18	1	1	0	3
2	0	0	0	0	0	0	0	0	18				
3	50	0	2	0	0	0	13	9	1	3	6	1	1
4	0	0	0	2	1	0	0	5	0				
5	0	16	0	0	0	0	1	0	2				
6	1	15	0	0	0	0	0	1	0	0	0	0	1
7	1	0	0	0	0	0		1	0	0	0		
8	0	0	0	0	0								
9	0	0	0	0	0	0	0	0	1	0			
10	0	0	0	0	0	0	0	0	1	0	0		
11	2	7	0	0	0	0	0	1	0		0		
12	0	0	0	0	0	0	0	1	1	0	0		
13	0	0	0	0	0	0	0	0	0	1	0		
14	2	0	0	0	0	0	0	0					
15	0	0	0	0	0	2	2	0	0	0	0	0	0
16	0	0	0	0	0	0	1	0	0	0	0		
17	0	0	0										
18	0	3	0	0	0	0	0	0	0	0	0		
19	0	0	0	0	0	0	0	0	0	0	0	0	
20	0	0	0	0	0	0	0	0	2	0	0	0	
21	0	0	0	0		0	0	0	0	0	0	3	
Summary: Urine RBC													
Average	2.7	2.0	0.1	0.1	0.1	0.1	0.9	1.0	2.4	0.4	0.5	0.8	1.3
Std Dev	10.9	4.8	0.4	0.4	0.2	0.5	3.1	2.3	5.7	0.8	1.6	1.3	1.3
Max	50	16	2	2	1	2	13	9	18	3	6	3	3
Min	0	0	0	0	0	0	0	0	0	0	0	0	0

Figure 46: SD & Range Charts for Urine RBC

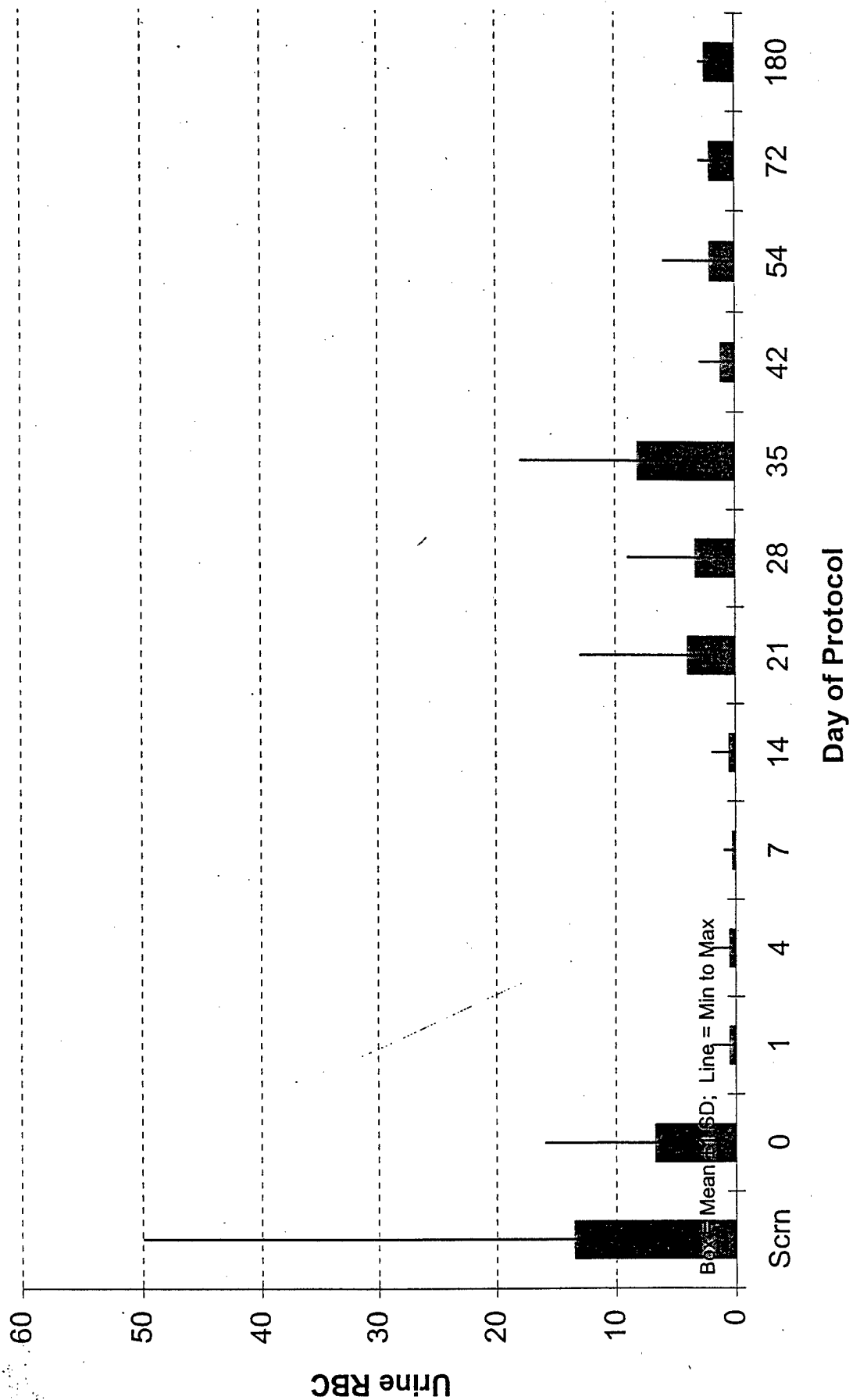


Table 11d  
Urinalysis: WBC

Blank= Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	0	0	0	0	0	0	0	0	2	0	0	0	2
02	1	0	0	0	0	0	0	2	0				
03	0	0	40	0	1	0	0	11	15	3	2	0	0
04	1	0	0	0	1	0	0	3	0	0			
05	0	0	0	0	0	0	1	0	1				
06	1	2	1	0	0	0	0	1	0	0	0	0	0
07	1	0	0	0	0	0	0	0		0	0	0	
08	0	0	0	3	0								
09	0	0	0	1	0	0	0	0	0	0	0		
10	0	0	4	5	0	0	0	0	2	0	0		
11	4	19	0	1	2	0	0	1	0	0	0		
12	0	3	0	0	0	0	0	1	1	0			
13	0	0	0	0	0	0	0	0	0	1	0		
14	0	0	0	0	0	0	0	0					
15	0	0	0	0	0	0	2	0	0	0	0		
16	0	0	0	0	0	0	2	0	0	0			
17	0	1	0	0	0	0	0	0	0	0			
18	0	0	0	0	0	0	0	0	0	0	0		
19	0	0	0	0	0	1	0	2	0	0	0		
20	0	8	0	0	0	0	0	0	1	0	2		
21	0	0	0	0	0	0	0	0	1	0	0	2	
Summary: Urine WBC													
Average	0.4	1.6	2.1	0.5	0.2	0.1	0.3	1.1	1.3	0.2	0.3	0.4	0.7
Std Dev	0.9	4.4	8.7	1.2	0.5	0.2	0.6	2.5	3.5	0.8	0.8	0.9	1.2
Max	4	19	40	5	2	1	2	11	15	3	2	2	2
Min	0	0	0	0	0	0	0	0	0	0	0	0	0



Figure 47: SD & Range Charts for Urine WBC

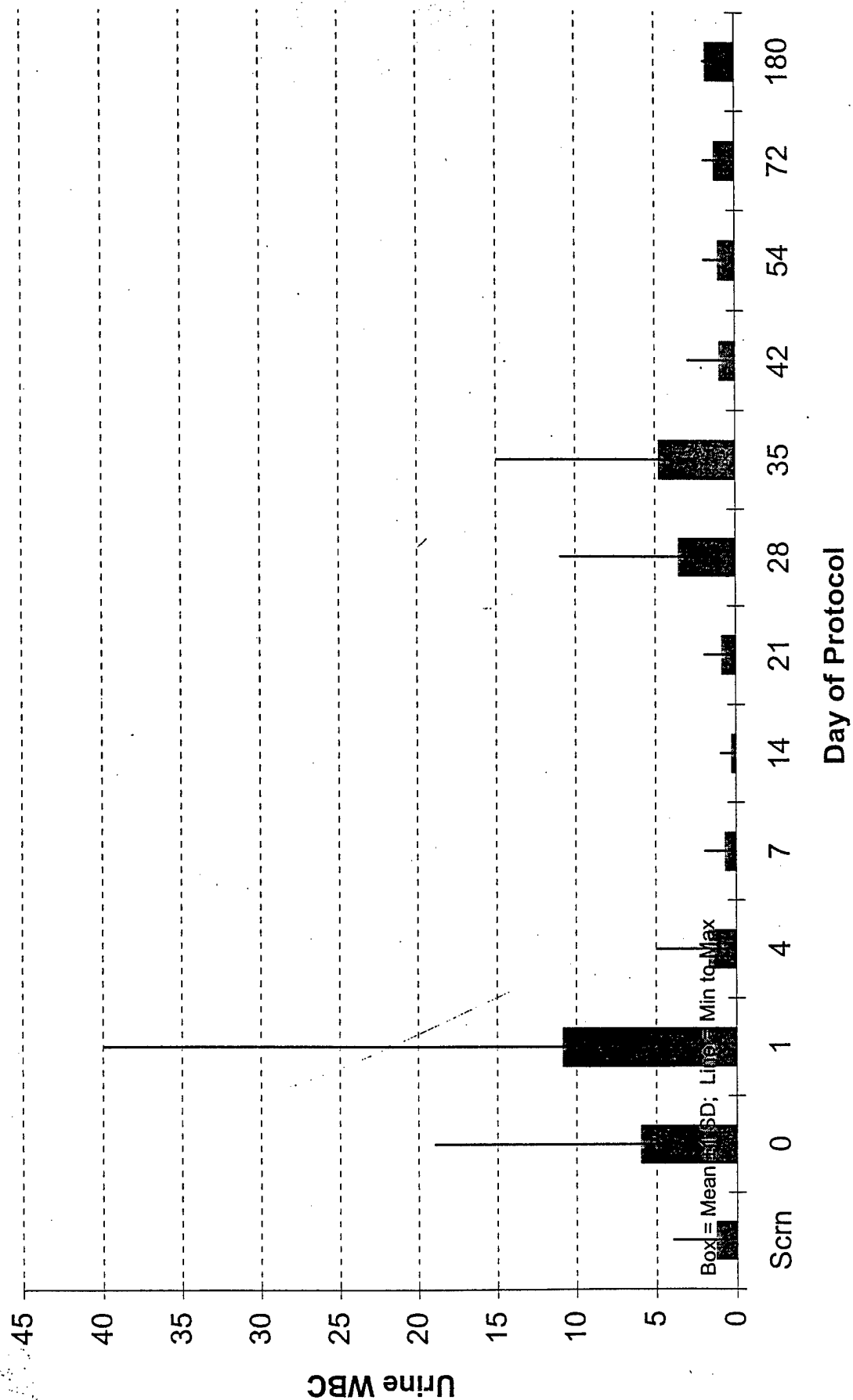
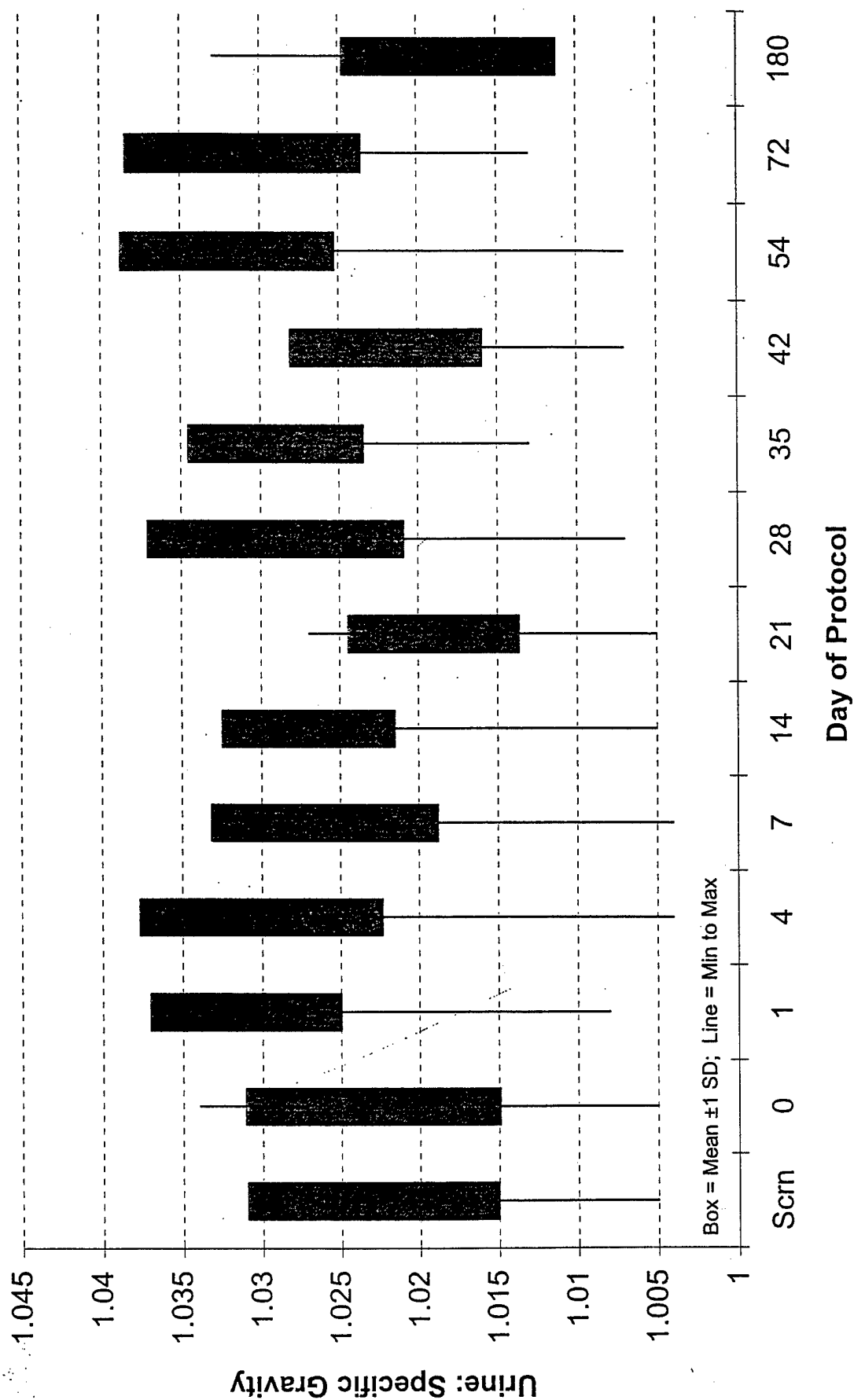


Table 11e  
Urinalysis: Specific Gravity

Blank = Not Obtained

Subject	Scrn	DAY 0	DAY 1	DAY 4	DAY 7	DAY 14	DAY 21	DAY 28	DAY 35	DAY 42	DAY 54	DAY 72	DAY 180
01	1.026	1.023	1.031	1.030	1.026	1.027		1.029	1.029	1.022	1.032	1.031	1.018
02	1.026	1.015	1.018	1.022	1.025	1.021	1.019	1.025	1.015				
03	1.009	1.019	1.016	1.007	1.019	1.005	1.005	1.019	1.022	1.022	1.019	1.019	1.021
04	1.027	1.016	1.018	1.026	1.026	1.014	1.027	1.030	1.028				
05	1.015	1.008	1.016	1.025	1.019	1.026	1.023	1.009	1.013				
06	1.028	1.012	1.026	1.026	1.022	1.023	1.025	1.027	1.027	1.021	1.025	1.026	1.020
07	1.034	1.022	1.023	1.008	1.009	1.011		1.027	1.029	1.028	1.030		
08	1.033	1.021	1.015	1.029	1.029								
09	1.029	1.007	1.026	1.029	1.020	1.019	1.020	1.016	1.028	1.022			
10	1.026	1.015	1.008	1.018	1.010	1.020	1.015	1.018	1.030	1.007	1.007		
11	1.030	1.026	1.019	1.026	1.019	1.025	1.019	1.027		1.027			
12	1.005	1.030	1.031	1.016	1.031	1.021	1.012	1.030	1.030	1.013	1.022		
13	1.025	1.025	1.016	1.019	1.022	1.016	1.018	1.028	1.026	1.026	1.026		
14	1.029	1.014	1.020	1.004	1.004	1.019	1.022	1.025		1.016	1.020		1.033
15	1.016	1.005	1.016	1.016	1.022	1.018	1.019	1.007	1.017	1.027			
16	1.009	1.015	1.026	1.029	1.025	1.025	1.027	1.029	1.028	1.027			
17	1.030	1.034											
18	1.018	1.017	1.021	1.016	1.010	1.021	1.020	1.010	1.025	1.022	1.021		
19	1.026	1.031	1.028	1.019	1.015	1.013	1.016	1.019	1.021	1.014	1.018		
20	1.027	1.028	1.025	1.022	1.020	1.017	1.016		1.032	1.017	1.028	1.013	
21	1.021	1.025	1.016	1.025		1.019	1.021	1.009	1.026	1.026	1.028	1.029	
Summary:	Urine: Specific Gravity												
Average	1.023	1.023	1.031	1.030	1.026	1.027	1.019	1.029	1.029	1.022	1.032	1.031	1.018
Std Dev	0.008	0.008	0.006	0.008	0.007	0.006	0.005	0.008	0.006	0.006	0.007	0.007	0.007
Max	1.027	1.034	1.031	1.030	1.031	1.027	1.027	1.030	1.032	1.028	1.032	1.031	1.033
Min	1.005	1.005	1.008	1.004	1.004	1.005	1.005	1.007	1.013	1.007	1.007	1.013	1.018

Figure 48: SD & Range Charts for Urine: Specific Gravity



**Figure 49a: Pharmacokinetics of Halofantrine Accumulation**

Subject	Accumulation Rate Constant (/day)		Accumulation Half-time (days)	
	Halo ( + )	Halo ( - )	Halo ( + )	Halo ( - )
1	0.101	0.086	6.89	8.10
2	0.058	0.048	11.88	14.30
4	0.392	0.730	1.77	0.95
5	0.160	0.159	4.33	4.35
7	0.139	0.211	4.97	3.28
8	0.058	0.060	12.00	11.63
9	0.126	0.116	5.49	5.99
10	0.038	0.056	18.26	12.43
11	0.262		2.65	
15	0.096	0.050	7.23	13.80
16	0.062	0.064	11.10	10.79
18	0.284	0.318	2.44	2.18
19	0.379	0.340	1.83	2.04
20	0.095	0.158	7.29	4.38
Mean:	0.161	0.184	7.01	7.25
SD:	0.120	0.191	4.80	4.82
p-value:	0.27		0.90	

Based on: exponential curve fit during administration of Halofantrine  
p-values from paired Student t-test

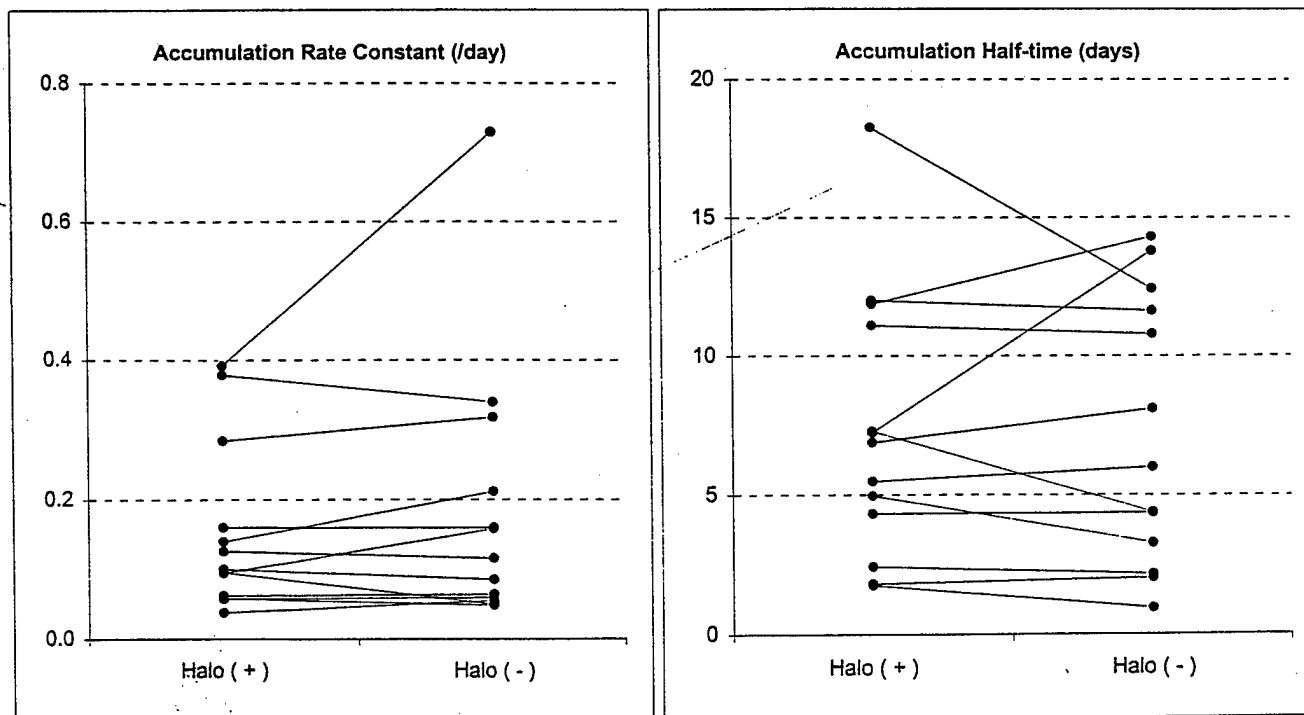


Figure 49b: Halofantrine Kinetics for Subject 01

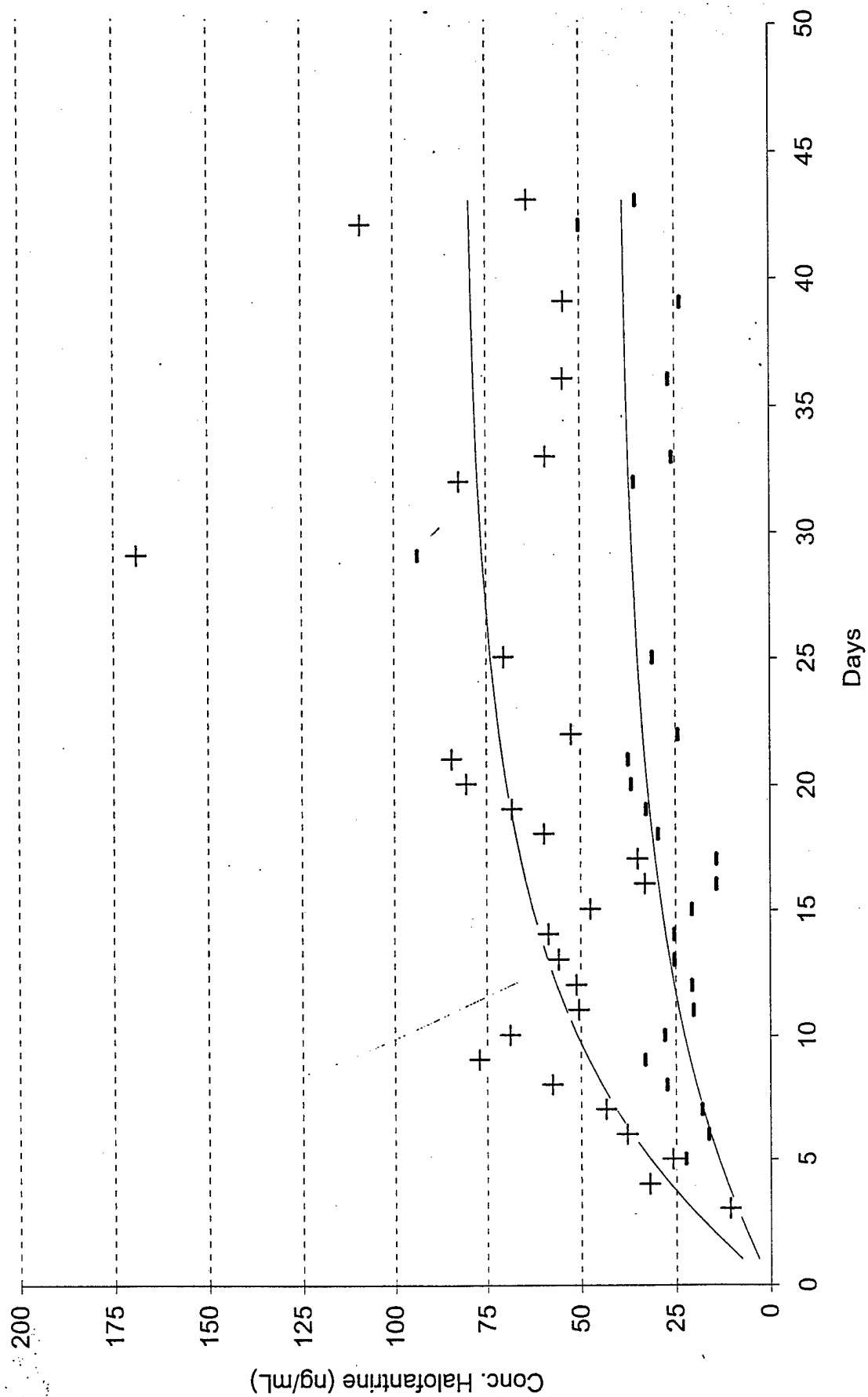


Figure 49c: Halofantrine Kinetics for Subject 02

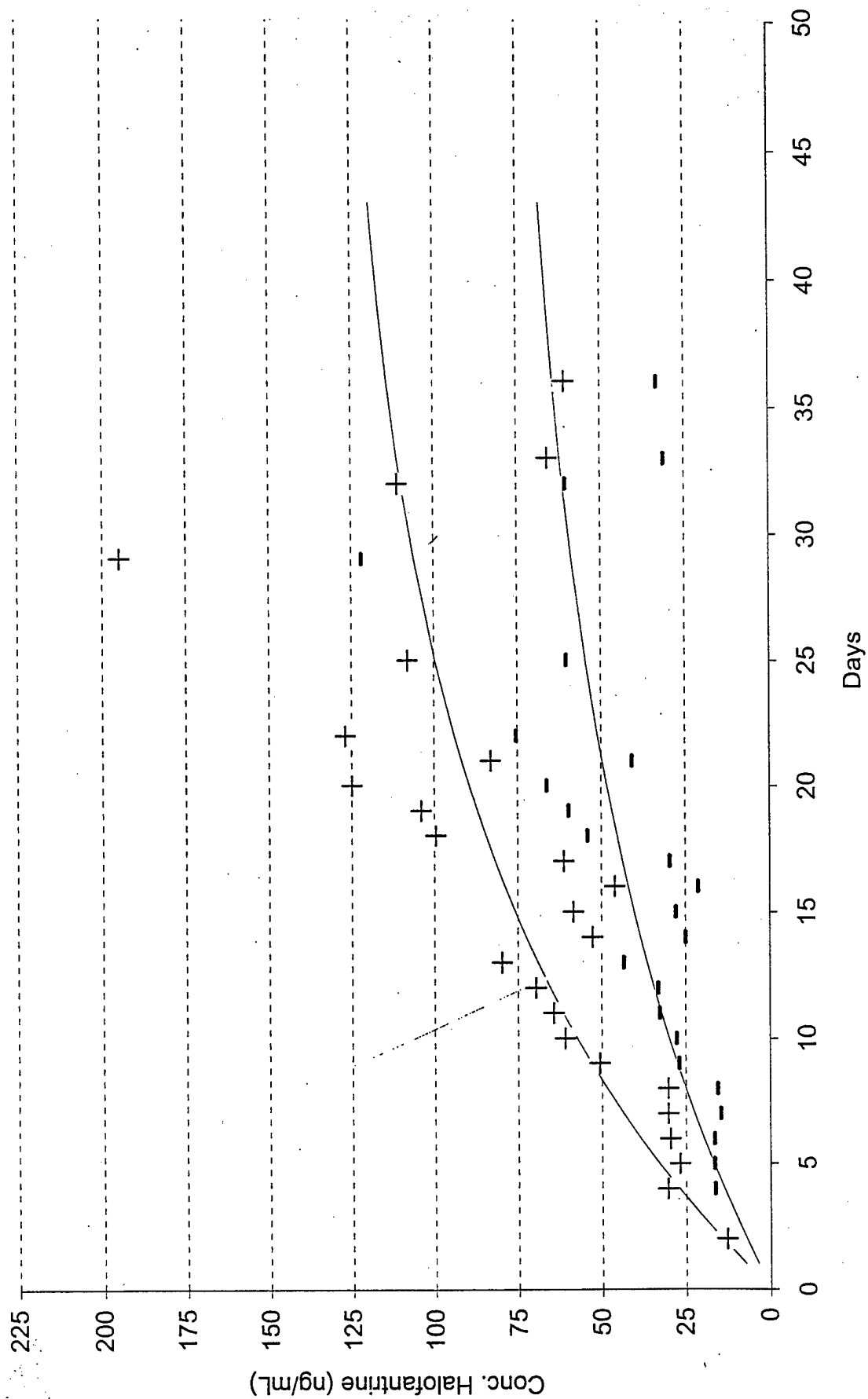


Figure 49d: Halofantrine Kinetics for Subject 04

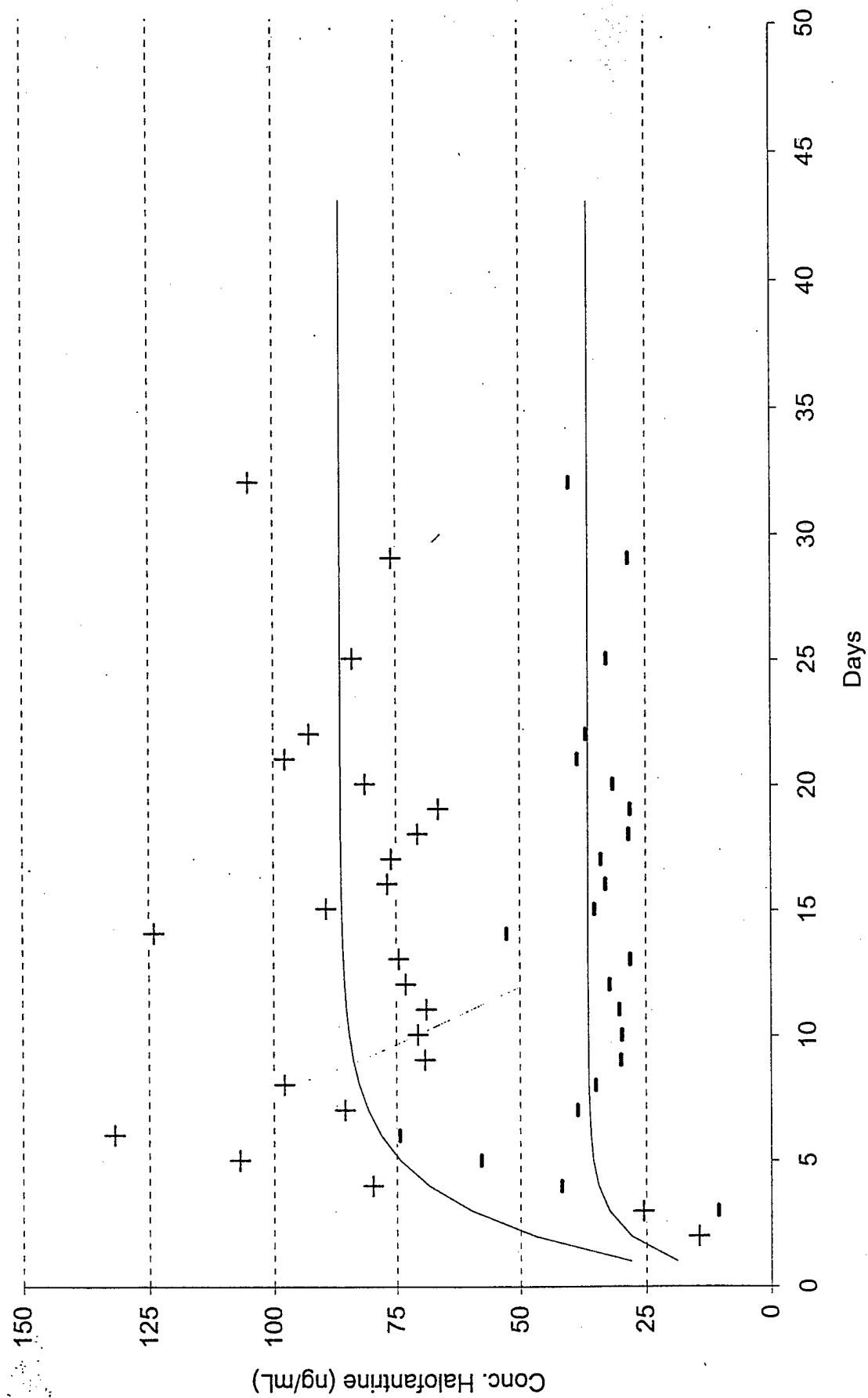


Figure 49e: Halofantrine Kinetics for Subject 05

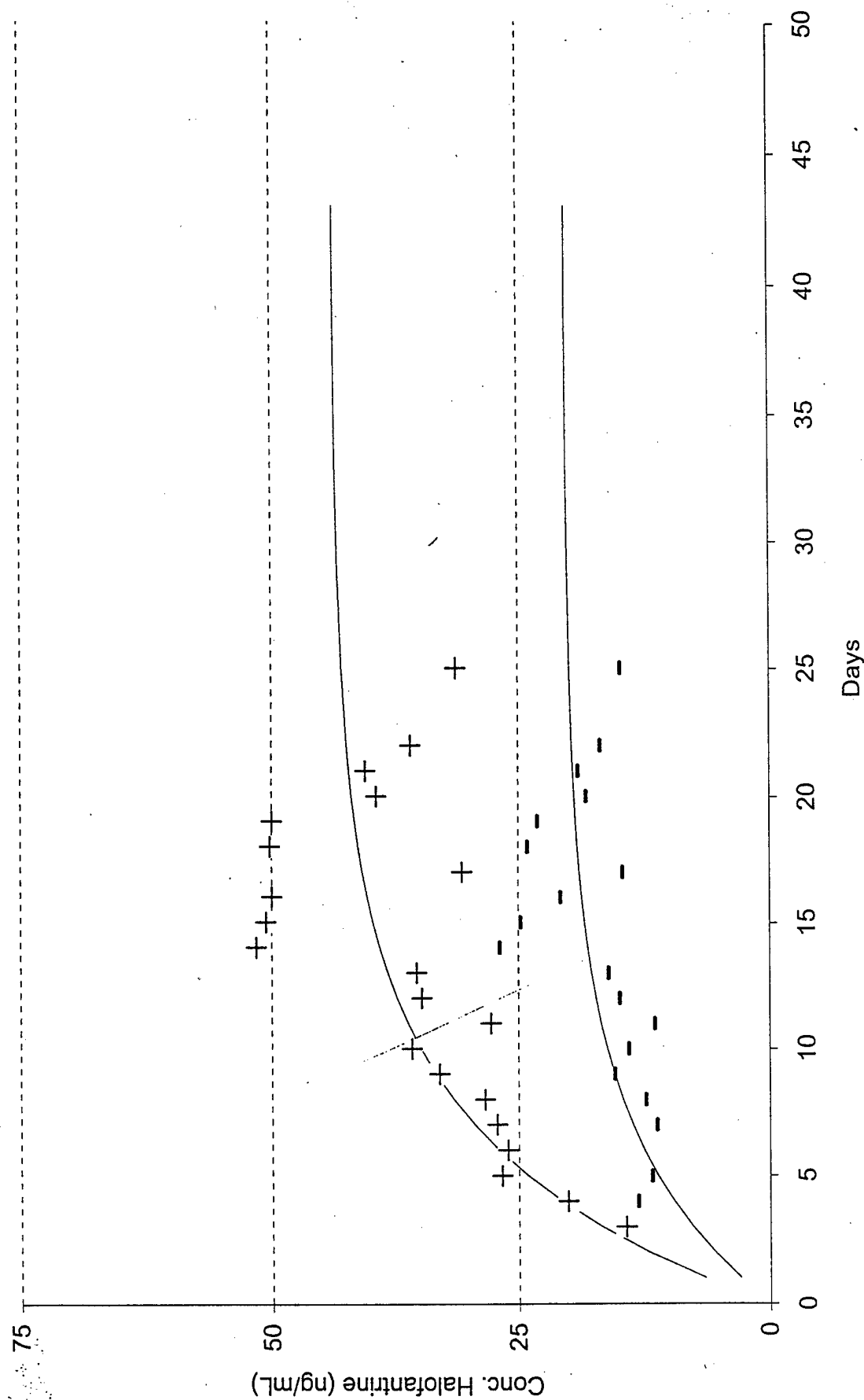




Figure 49f: Halofantrine Kinetics for Subject 07

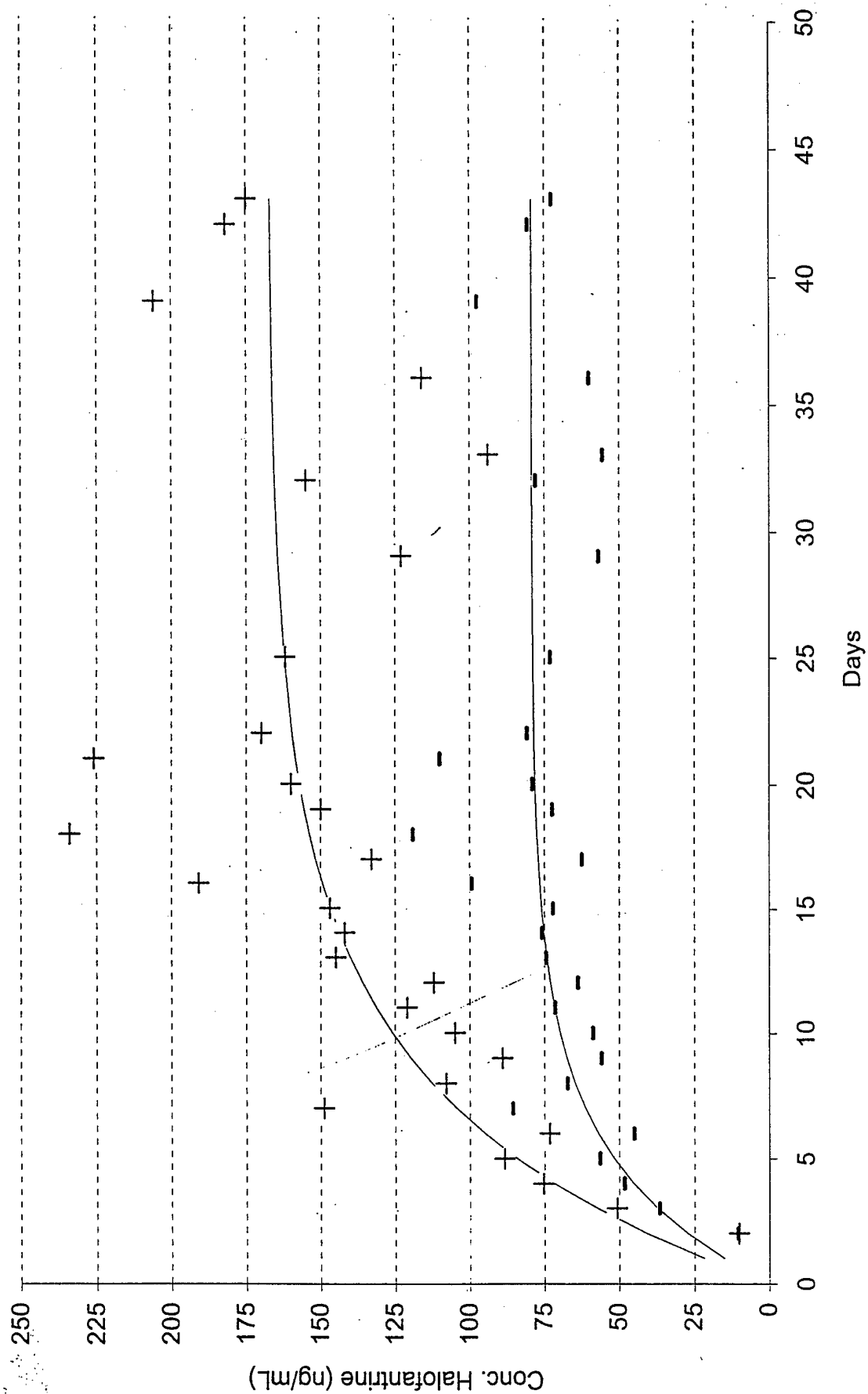


Figure 49g: Halofantrine Kinetics for Subject 08

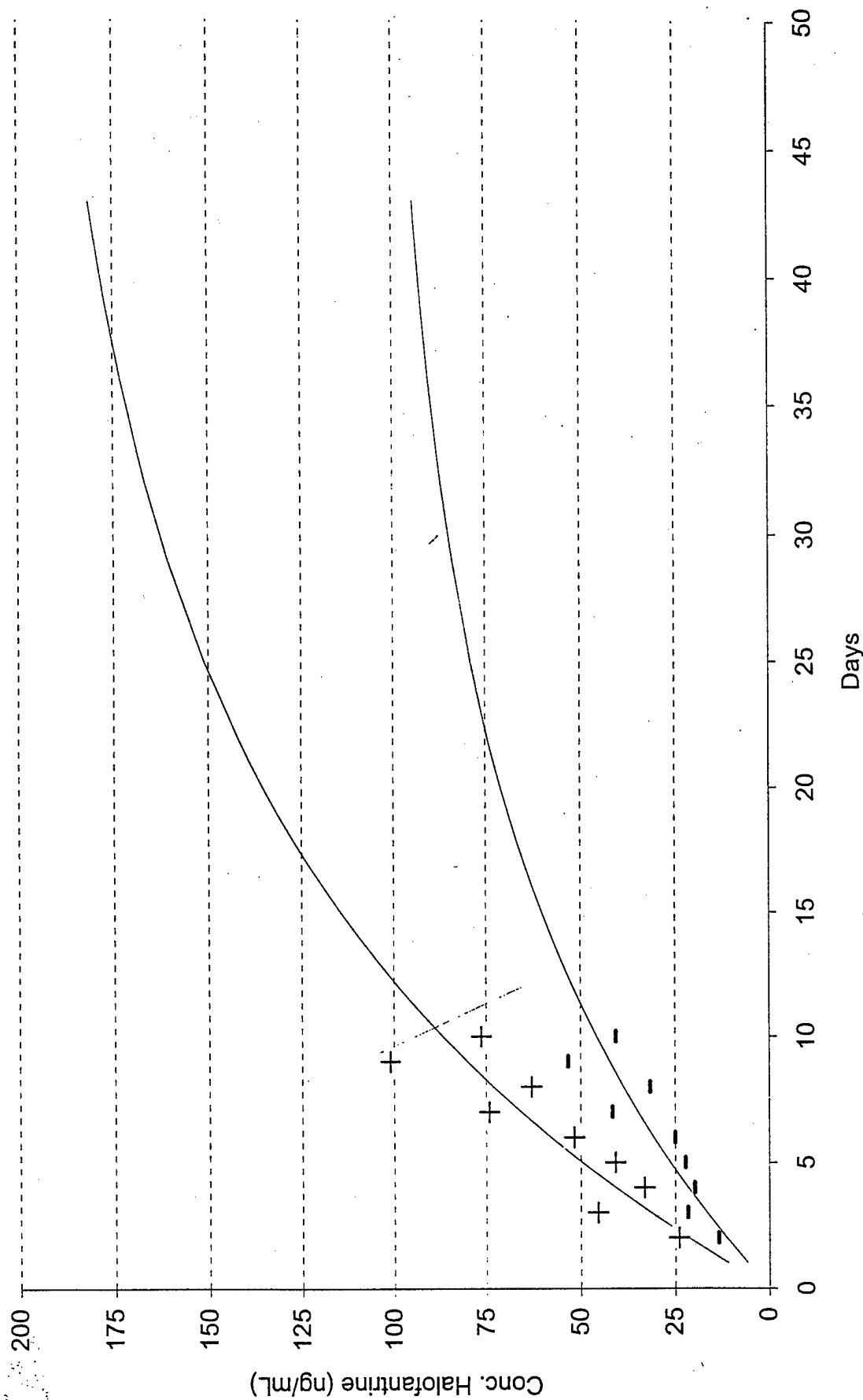


Figure 49h: Halofantrine Kinetics for Subject 09

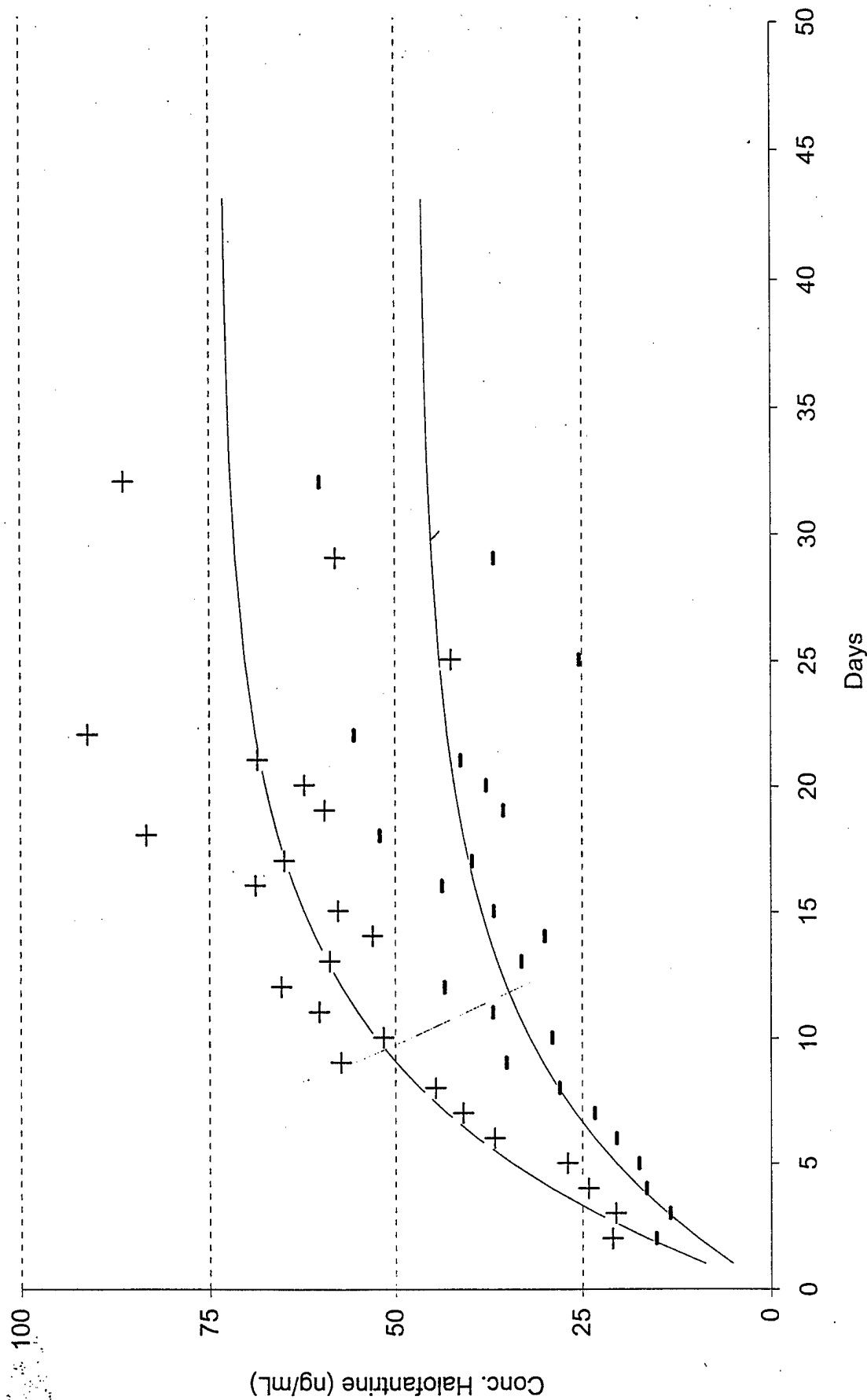


Figure 49j: Halofantrine Kinetics for Subject 10

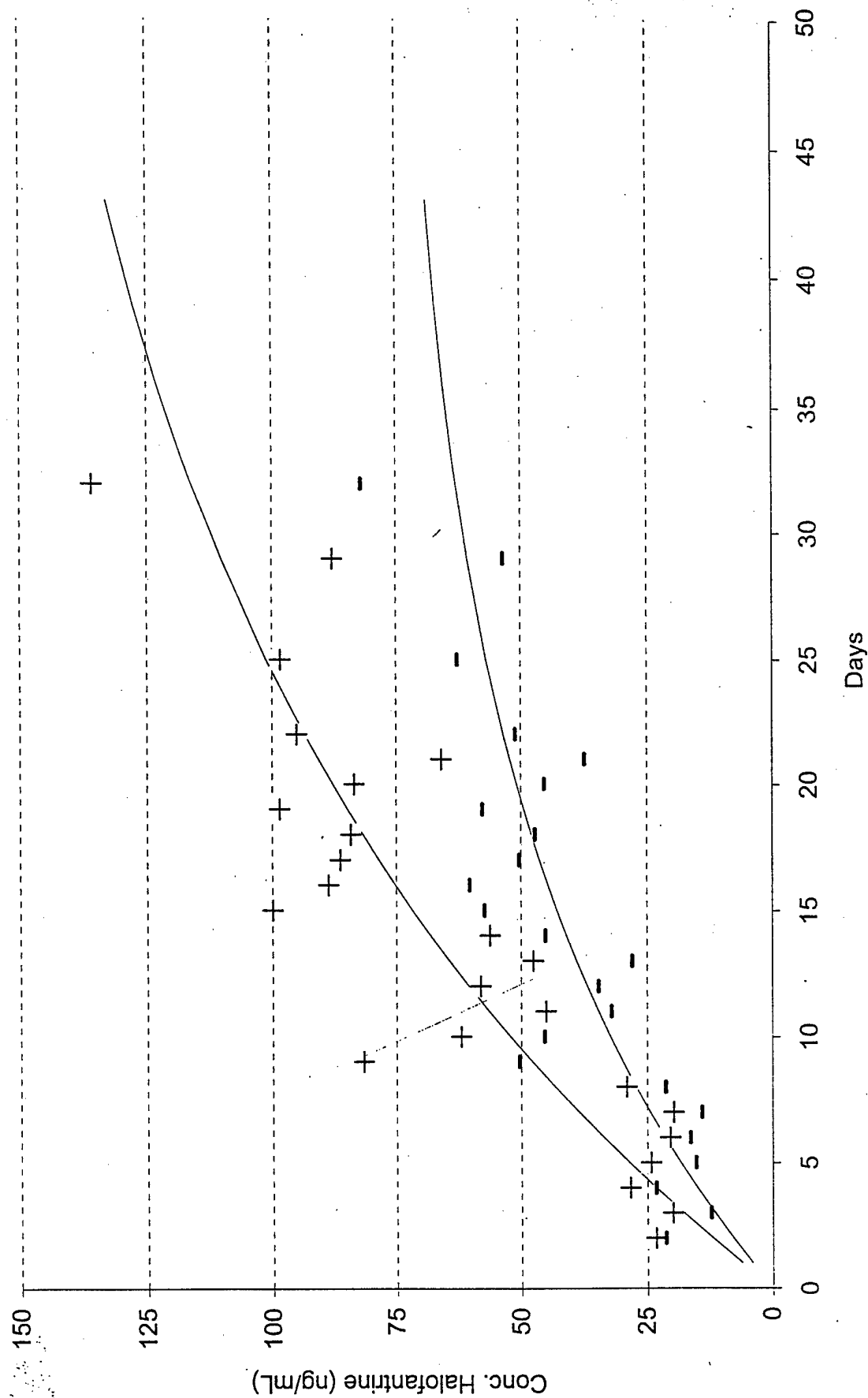


Figure 49j: Halofantrine Kinetics for Subject 11

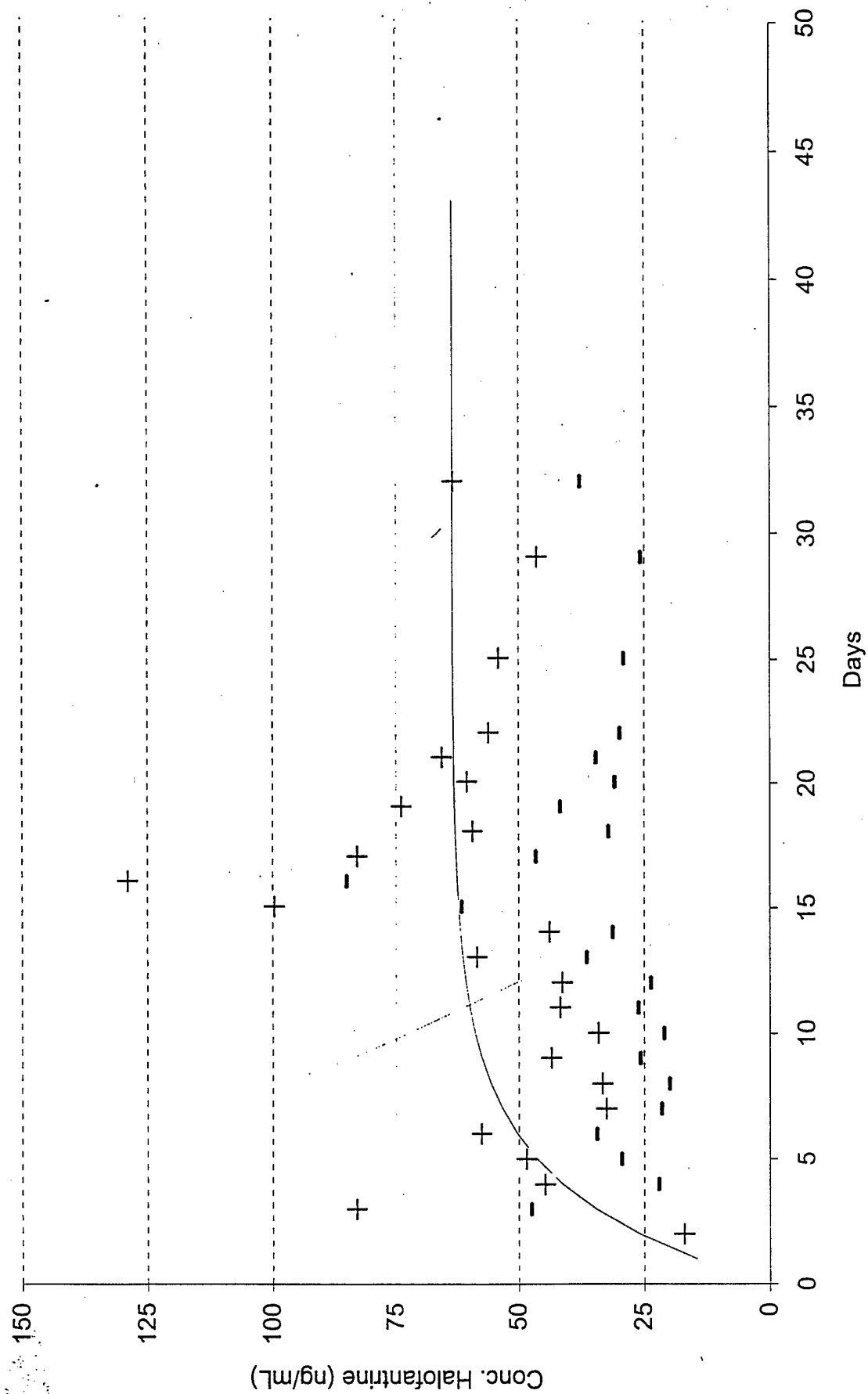


Figure 49k: Halofantrine Kinetics for Subject 14

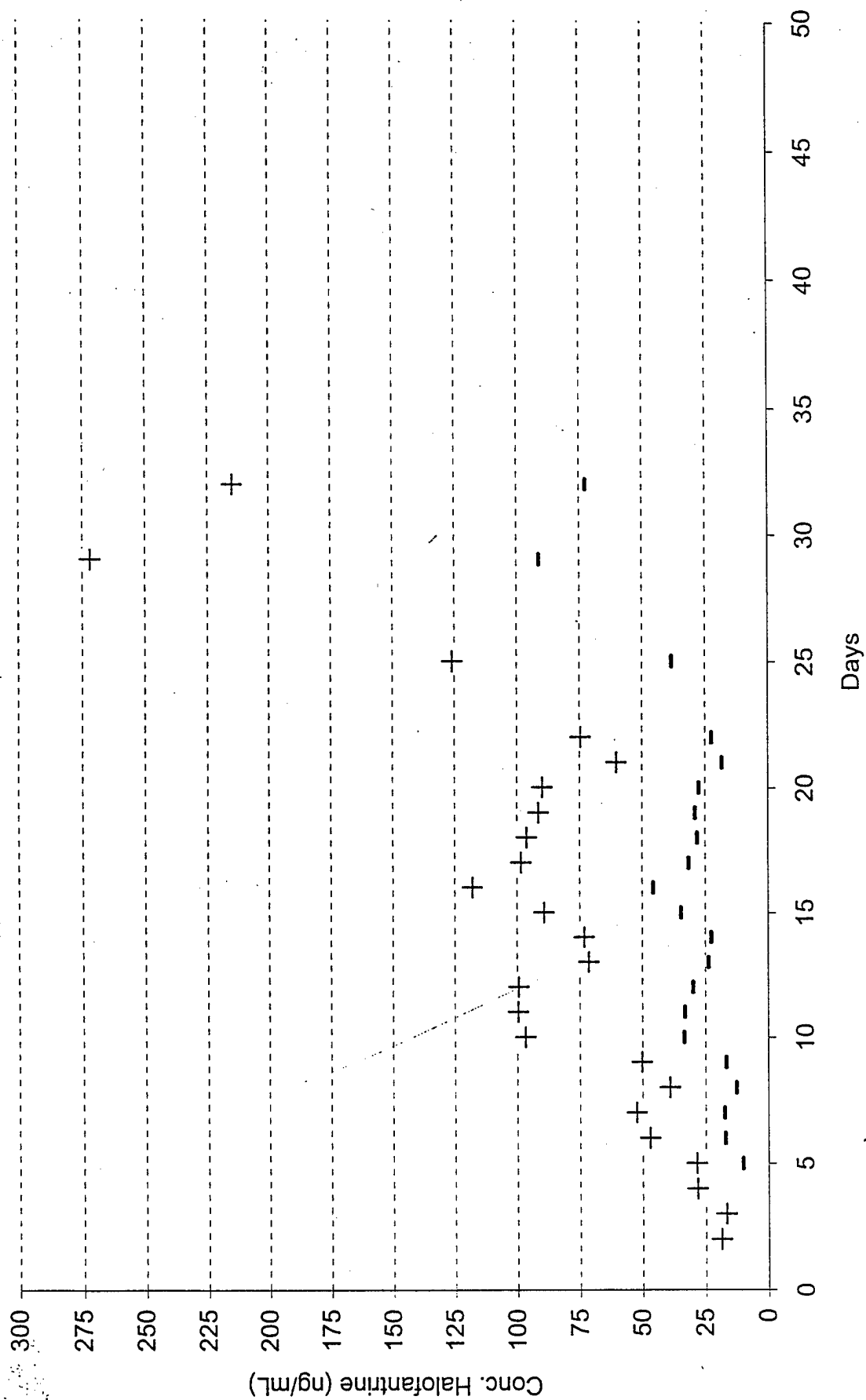


Figure 49L: Halofantrine Kinetics for Subject 15

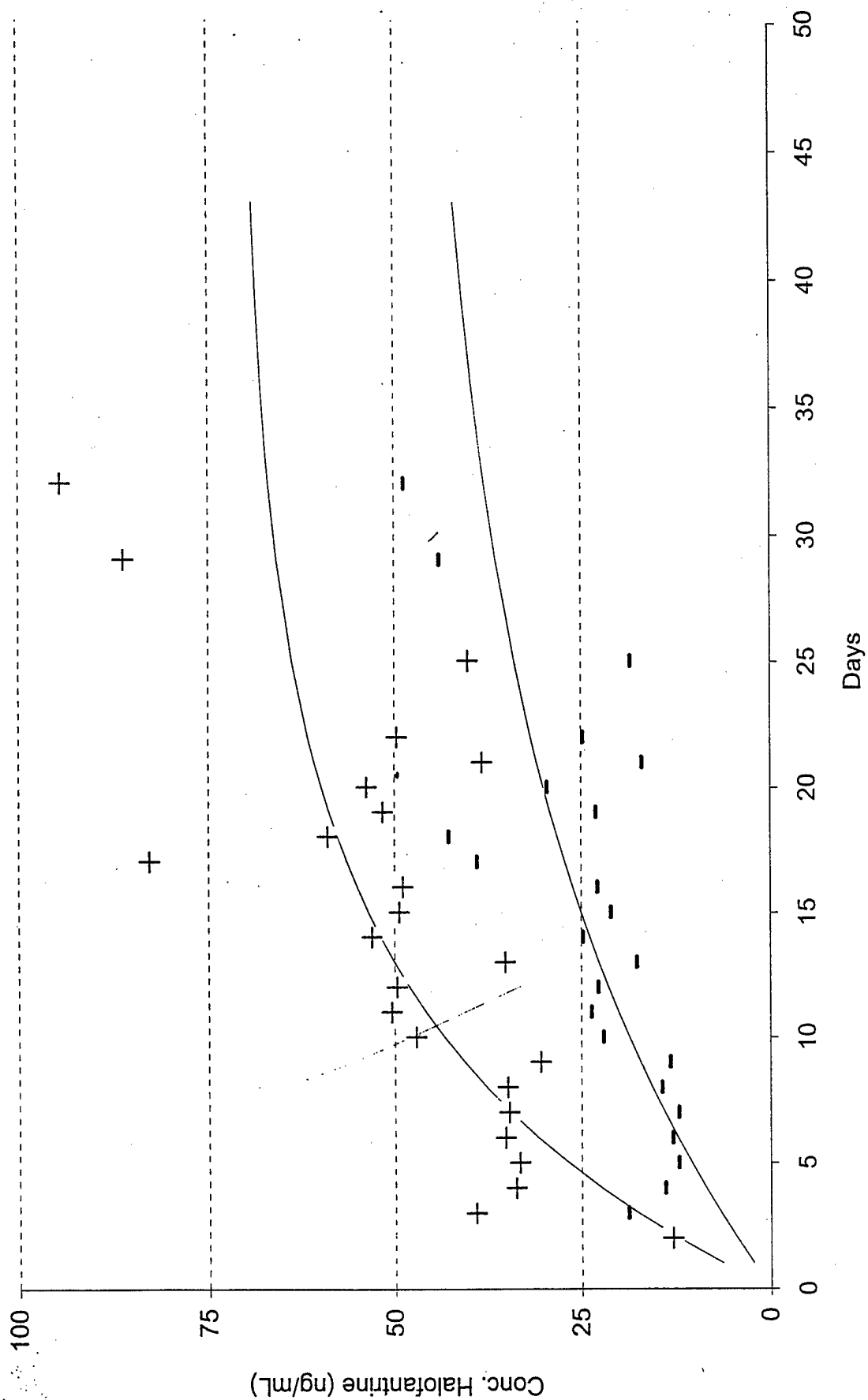


Figure 49m: Halofantrine Kinetics for Subject 16

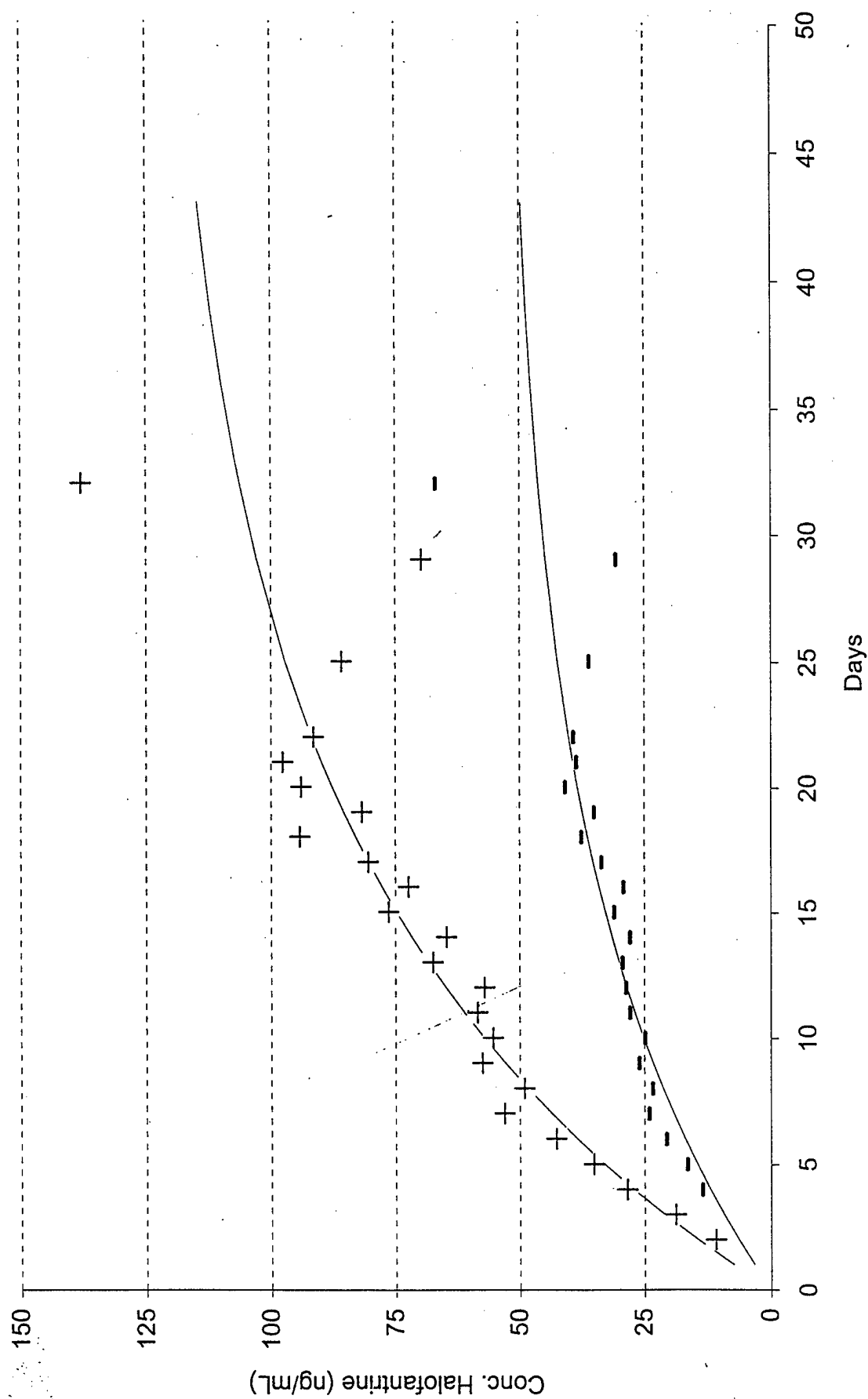




Figure 49n: Halofantrine Kinetics for Subject 18

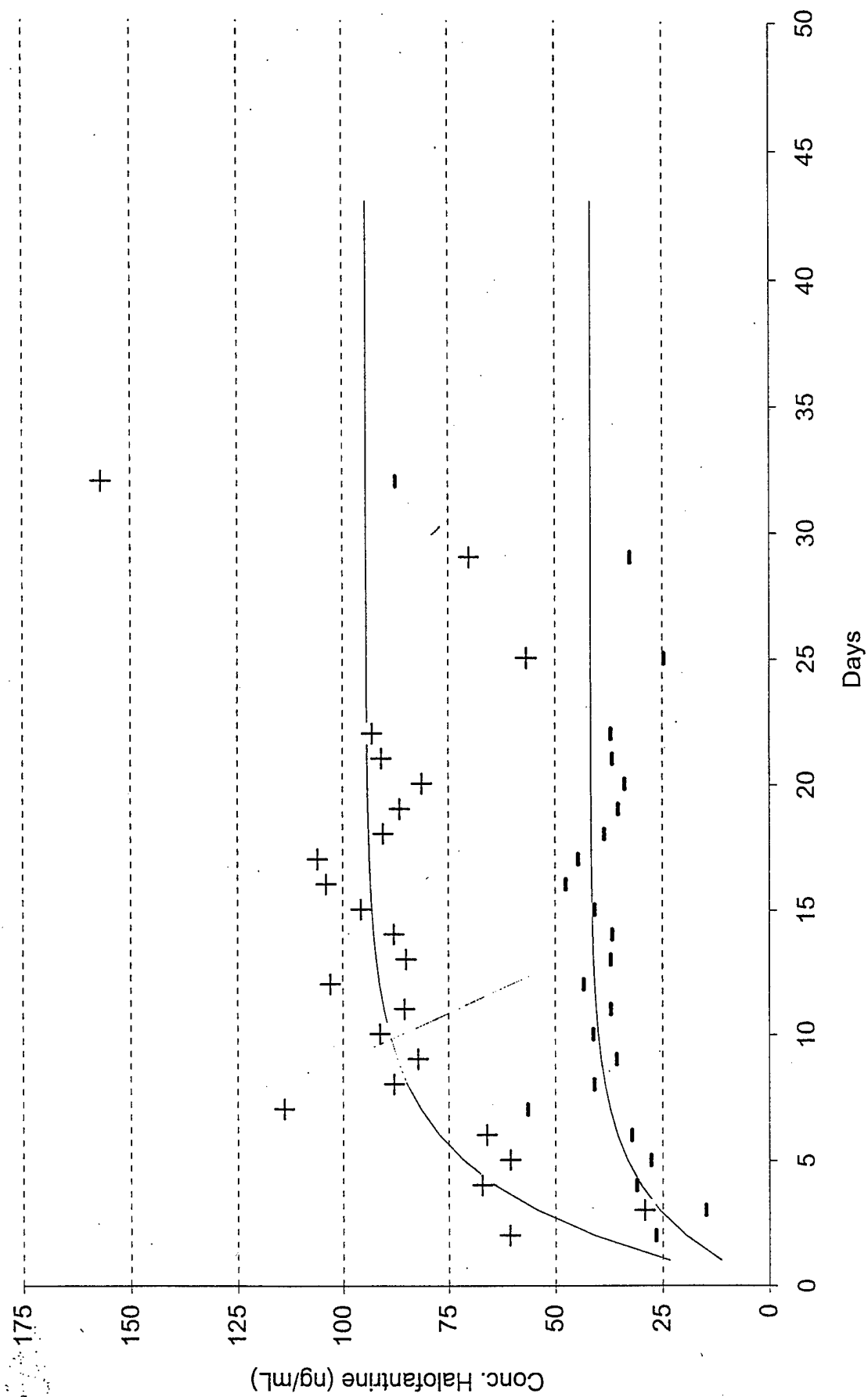


Figure 49o: Halofantrine Kinetics for Subject 19

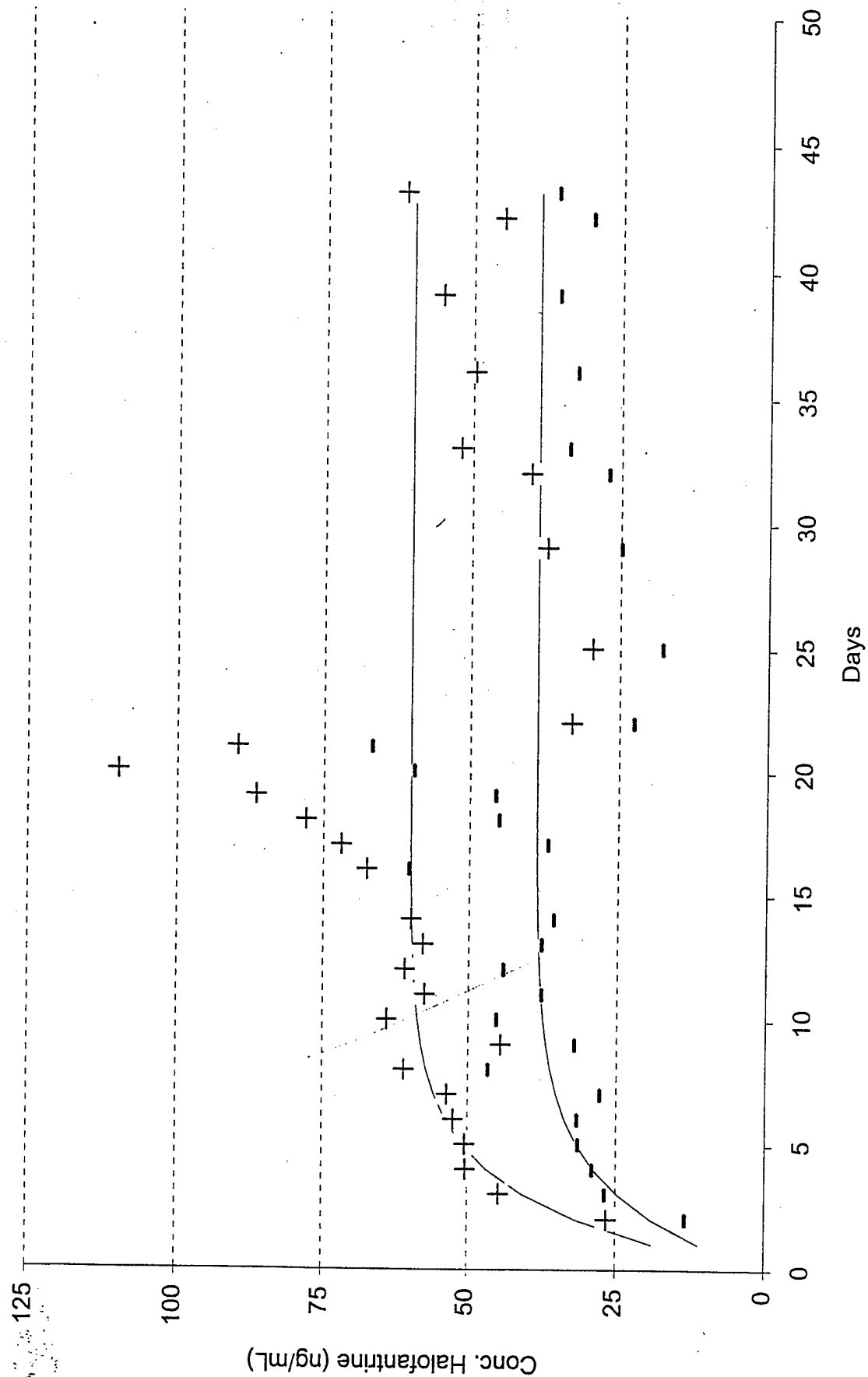
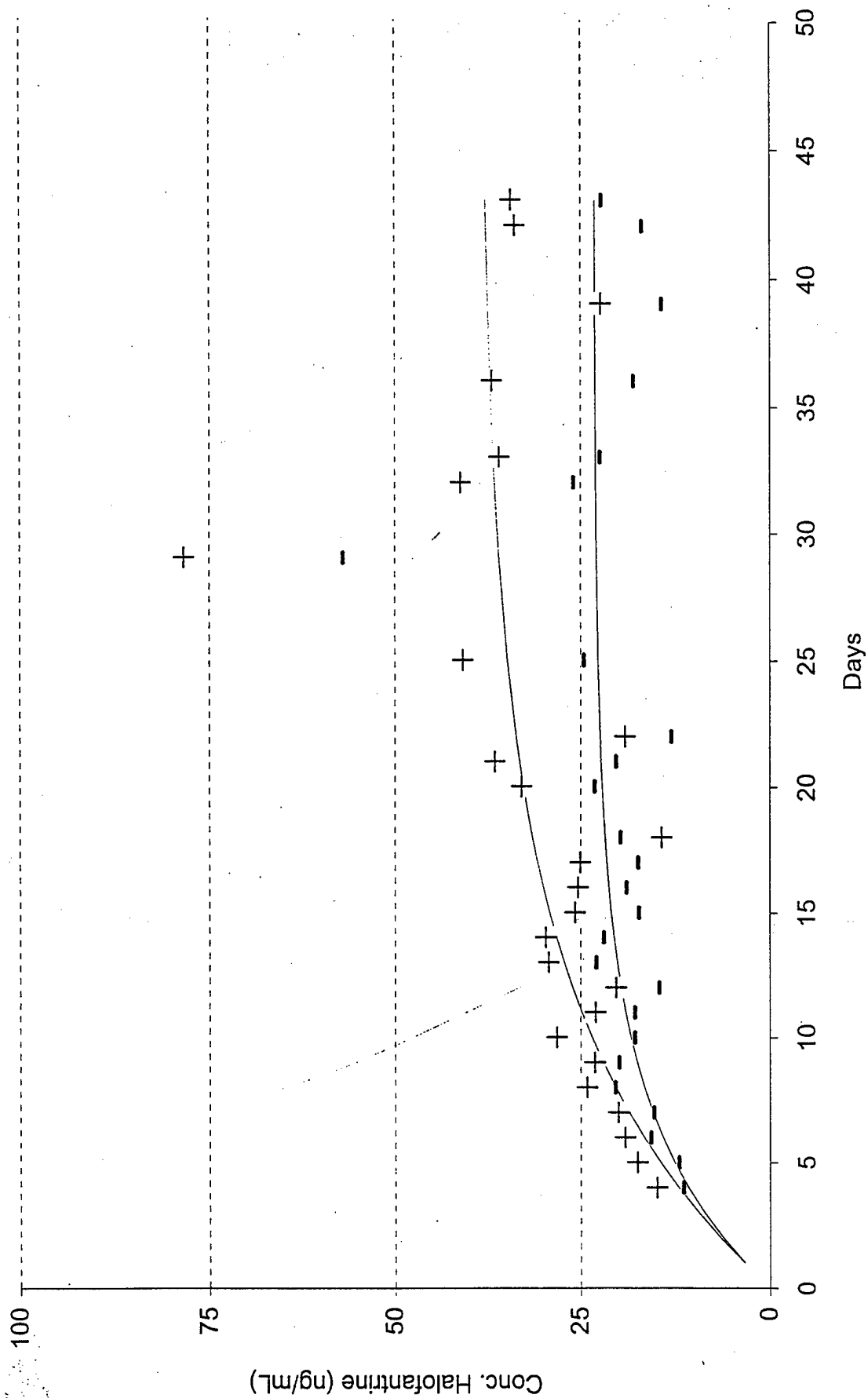


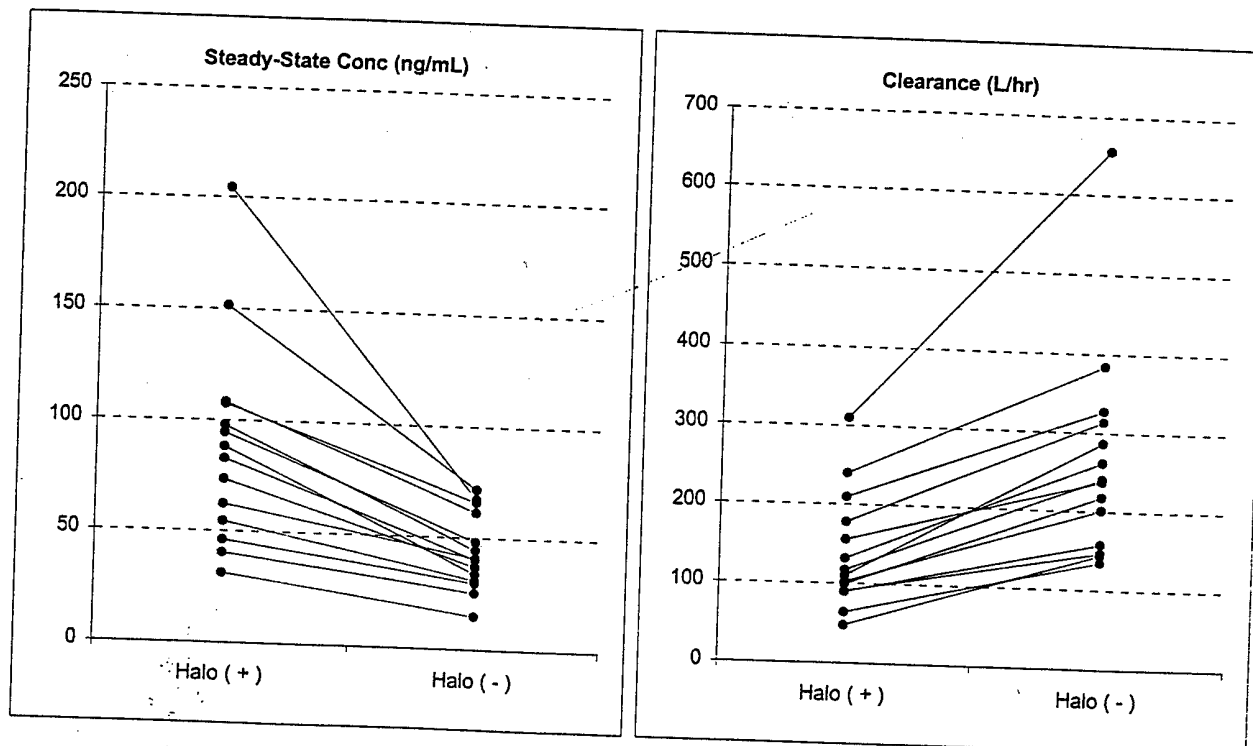
Figure 49p: Halofantrine Kinetics for Subject 20



**Figure 50: Pharmacokinetics of Halofantrine Clearance**

Subject	Steady-State Conc (ng/mL)		Clearance (L/hr)	
	Halo ( + )	Halo ( - )	Halo ( + )	Halo ( - )
1	82.9	40.3	117.1	241.0
2	108.1	61.5	89.8	157.9
4	88.3	33.8	109.9	287.0
5	31.3	14.8	310.2	656.0
7	151.6	71.9	64.0	135.1
9	62.3	40.8	155.8	238.0
10	107.4	66.1	90.4	146.9
11	54.6	30.9	177.7	314.2
14	204.3	67.4	47.5	144.0
15	73.6	37.0	131.9	262.2
16	97.9	44.6	99.2	217.8
18	94.6	48.3	102.6	201.1
19	46.3	29.7	209.8	327.4
20	40.5	25.3	240.0	384.5
Mean:	88.8	43.7	139.0	265.2
SD:	46.2	17.3	73.0	135.4
p-value:	0.000		0.000	

Based on an average infusion rate of 233 mg/day of each isomer  
p-values from paired Student t-test



Blank = Not Obtained

Table 12a-1  
ECG: Rate

Units: BPM

Subj	Scrn	Day 1 Pre	Day 1 .5hr	Day 1 1hr	Day 1 2hr	Day 1 3hr	Day 1 4hr	Day 1 6hr	Day 1 8hr	Day 1 10hr	Day 1 12hr	Day 2 Pre	Day 3 Pre	Day 4 Pre	Day 4 2hr	Day 4 4hr
01	87	58	67	72	59	61	67	69	68	74	70	67	62	65	60	71
02	71	55	51	55	55	66	59	57	65	63	58	58	64	57	68	64
03	60	60	58	55	59	58	63	58	60	56	53	60	58	54	55	62
04	79	69	71	69	66	64	67	71	69	67	73	70	64	70	75	77
05	60	56	51	52	58	51	52	61	58	60	60	56	50	57	54	61
06	72	64	59	57	55	69	66	54	55	64	54	53	54	59	54	70
07	58	46	41	41	51	52	47	44	46	45	46	41	49	59	50	66
08	61	55	51	57	57	57	59	59	54	51	61	54	53	50	55	62
09	51	49	50	51	52		55	63	57	58	57	50	48	58	53	63
10	68	59	59	62	64	72	70	67	64	75	62	65	64	66	71	77
11	92	84	86	83	88	89	98	86	96	93	85	76	64	67	66	71
12	59	60	60	58	58	70	77	63	65	67	60	57	52	54	51	63
13	51	46	44	46	45	56	54	52	57	53	51	48	44	46	52	52
14	49	45	45	46	44	48	47	44	43	47	44	45	44	45	47	49
15	68	65	67	60	74	62	83	73	66	66	64	73	67	57	72	66
16	74	78	72	70	66	76	72	69	60	66	71	70	65	78	71	77
17	55	59	53	57	59	67	68	67								
18	68	58	56	55	58	65	63	64	67	76	66	58	61	63	62	72
19	69	58	61	62	61	60	69	68	60	72	64	68	63	73	74	82
20		50	46	52	52	52	64	62	55	54	55	49	58	50	53	59
21	67	62	58	59	59	63	70	69	65	65	66	64	57	63	63	64
Summary:	ECG: Rate, BPM															
Average	66	59	57	58	59	63	65	63	62	64	61	59	57	60	60	66
Std Dev	11	10	11	10	10	10	12	10	11	11	10	10	07	09	09	08
Max	92	84	86	83	88	89	98	86	96	93	85	76	67	78	75	82
Min	49	45	41	41	44	48	47	44	43	45	44	41	44	45	47	49

Units: BPM

Table 12a-2  
ECG: Rate

Blank = Not Obtained

Subj	Day 4 6hr	Day 4 8hr	Day 4 12hr	Day 5 PRE	Day 6 Pre	Day 7 Pre	Day 7 2hr	Day 7 4hr	Day 7 6hr	Day 7 8hr	Day 7 12hr	Day 8 Pre	Day 9 Pre	Day 10 Pre	Day 11 Pre	Day 12 Pre
01	86	64	74	62	67	56	64	62	65	57	69	67	59	58	53	61
02	79	69	71	64	62	61	55	62	68	106	80	61	53	54	57	61
03	60	68	62	52	54	57	62	65	62	60	61	61	54	54	56	68
04	71	93	79	68	69	74	66	71	78	72	71	69	75	68	73	75
05	68	59	52	46	55	54	49	54	67	52	55	55	50	50	49	56
06	66	68	65	57	53	65	54	75	70	58	64	59	58	54	64	61
07	51	52	55	47	67	59	54	72	64	57	69	58	65	65	62	57
08	61	58	58	54	51	52	54	62	58	57	60	56	56	57		
09	59	56	58	51	49	53	51	67	61	56	60	50	57	54	48	53
10	69	67	76	65	75	68	73	77	74	94	71	72	60	90	75	67
11	67	74	73	65	64	64	61	74	67	65	65	62	61	60	64	60
12	63	56	56	64	64	55	56	65	66	65	64	66	72	61	62	61
13	60	51	54	47	53	50	50	59	52	57	61	53	50	47	46	45
14	47	48	41	45	48	47	45	51	50	46	46	48	45	45	42	47
15	63	57	55	59	66	69	63	67	58	62	61	58	59	57	62	55
16	79	65	73	79	64	65	68	78	76	73	69	74	67	66	78	65
17																
18	70	66	64	63	61	70	65	77	78	72	68	63	67	62	65	61
19	79	76	64	68	66	63		73	69	68	62	56	66	64	57	62
20	58	55	59	51	53	51	55	64	59	58	55	55	56	52	56	55
21	75	66	67	64	60	57	55	65	64	68	71	58	59	56	58	56
Summary:																
Average	67	63	63	59	60	60	58	67	65	65	64	60	59	59	59	59
Std Dev	10	10	10	09	08	08	07	08	08	14	07	07	08	10	10	07
Max	86	93	79	79	75	74	73	78	78	106	80	74	75	90	78	75
Min	47	48	41	45	48	47	45	51	50	46	46	48	45	45	42	45

Blank = Not Obtained

Table 12a-3  
ECG: Rate

Units: BPM

Subj	Day 13 Pre	Day 14 Pre	Day 14 2hr	Day 14 4hr	Day 14 6hr	Day 14 8hr	Day 14 12hr	Day 15 Pre	Day 16 Pre	Day 17 Pre	Day 18 Pre	Day 19 Pre	Day 20 Pre	Day 21 Pre
01	66	59	59	59	64	66	64	57	63	57	65	80	64	68
02	52	54	67	60	76	67	71	63	53	63	54	54	56	58
03	64	68	62	56	70	63	65	61	60	61	59	59	52	57
04	68	73	74	76	83	83	84	79	76	77	98	81	76	75
05	58	53	54	65	58	52	51	51	53	54	58	56	54	52
06	57	56	54	71	68	65	63	66	61	68	66	60	59	60
07	59	68	61	68	72	84	65	70	63	67	64	65	67	85
08														
09	56	45	59	60	55	54	57	53	50	56	50	49	56	51
10	59	75	64	75	73	80	65	62	69	61	88	79	67	71
11	54	66	63	74	70	71	79	61	64	62	62	64	67	65
12	63	59	59	56	57	63	76	67	61	63	67	65	59	62
13	46	42	49	60	44	91	58	50	50	49	55	48	43	44
14	42	45	44	51	51	48	49	46	44	46	46	45	50	49
15	58	55	56	71	65	58	56	54	51	52	61	69	57	54
16	81	64	65	78	80	65	72	70	71	78	70	70	71	75
17														
18	70	65	68	89	95	82	85	68	67	62	67	65	68	74
19	58	62						63	56	57	57	61	60	57
20	55	54	56	59	58	62	63	54	53	55	54	55	54	58
21	58	52	57	64	69	61	68	55	54	55	59	60	55	54
Summary:														
Average	59	59	60	66	67	68	66	61	59	60	63	62	60	62
Std Dev	09	09	07	10	12	12	10	08	08	08	12	10	08	11
Max	81	75	74	89	95	91	85	79	76	78	98	81	76	85
Min	42	42	44	51	44	48	49	46	44	46	46	45	43	44

Units: BPM

Table 12a-4  
ECG: Rate

Blank = Not Obtained

Subj	Day 21 2hr	Day 21 4hr	Day 21 6hr	Day 21 8hr	Day 21 12hr	Day 22 Pre	Day 25 Pre	Day 29 Pre	Day 32 Pre	Day 36 Pre	Day 39 Pre	Day 42 Pre	Day 42 .5hr	Day 42 1hr
01	56	75	71	76	75	82	73	73	75	63	72	57	63	59
02	51	53	64	72	73	72	77	68	109	80	68			
03	49	51	56	53	63	54	52	59	62	58	66	56	61	62
04	75	88	82	85	78	85	81	72	75	75				
05	54	63	55	57	56	55	53							
06	64	76	78	76	69	70	77	67	73	62	64	58	57	56
07	68	68	69	66	69	65	79	59	75	53	68	59	55	56
08														
09	61	64	63	61	60	60	72	59	55	54	50	47	58	46
10	65	80	82	76	67	72	75	84	72	57	60	69	59	63
11	70	80	73	74	72	66	71	77	70		73	64	63	60
12	59	66	67	68	67	65	74	70	70	61	70	59	62	59
13	43	52	46	49	47	54	62	50	60	54	56	47	48	49
14	57	52	51	50	49	50	59	58	54	57	56			
15	56	67	63	58	67	55	76	75	71	72	68	60	57	62
16	64	89	77	73	75	72	76	67	70	72	75	67	63	61
17														
18	72	83	85	85	77	72	80	88	81			57	59	58
19	59	76	69	65	63	67	60	61	68	69	67	64	61	60
20	56	64	64	66	60	59	54	56	54	51	54	58	53	54
21	54	61	58	57	72	56	54	56	61	60	52	52	57	54
Summary:														
Average	60	69	67	67	66	65	69	67	70	62	64	58	58	57
Std Dev	08	12	11	11	09	10	10	10	13	09	08	06	04	05
Max	75	89	85	85	78	85	81	88	109	80	75	69	63	63
Min	43	51	46	49	47	50	52	50	54	51	50	47	48	46



Units: BPM

Table 12a-5  
ECG: Rate

Blank = Not Obtained

Subj	Day 42 2hr	Day 42 3hr	Day 42 4hr	Day 42 6hr	Day 42 8hr	Day 42 10hr	Day 42 12hr	Day 43 AM	Day 44 AM	Day 45 AM	Day 48 AM	Day 51 AM	Day 54 AM	Day 57 AM
01	63	86	70	67	69	76	71	56	58	60	59	54	68	64
02														
03	57	62	62	65	53	56	58	73	70	74	69	64	65	61
04														
05														
06	58	58	78	60	59	59	53	59	57	55	64	61	64	63
07	56	48	59	47	54	59	55	36		74	68	65	83	78
08														
09	51	55	54	49	53	53	52	50	55		54	60	56	69
10	70	87	76	63	59	70	72	71	79		70	81	81	
11	64	75	77	71	68	68	70	68	68	79				
12	55	68	61	55	55	58	60	58	61	55	67	74	60	78
13	52	49	51	45	46	49	49	50	62	64	49	59	62	62
14														
15	64	73	71	68	68	71	75	75	69	63	61	78	68	63
16	57	79	68	76	73	73	75	78	96					
17														
18	57	65	64	59	56	62	60	57	73	75		80	86	81
19	61	67	68	63	62	63	62	62	69	65	74	80	74	63
20	57	59	66	62	63	58	55	58	54	53	58	65	58	51
21	58	57	63	57	65	64	57	55	71	70	74	93	71	72
Summary:														
Average	59	66	66	60	60	63	62	60	67	66	64	70	69	67
Std Dev	05	12	08	09	08	08	09	11	11	09	08	11	10	09
Max	70	87	78	76	73	76	75	78	96	79	74	93	86	81
Min	51	48	51	45	46	49	49	36	54	53	49	54	56	51

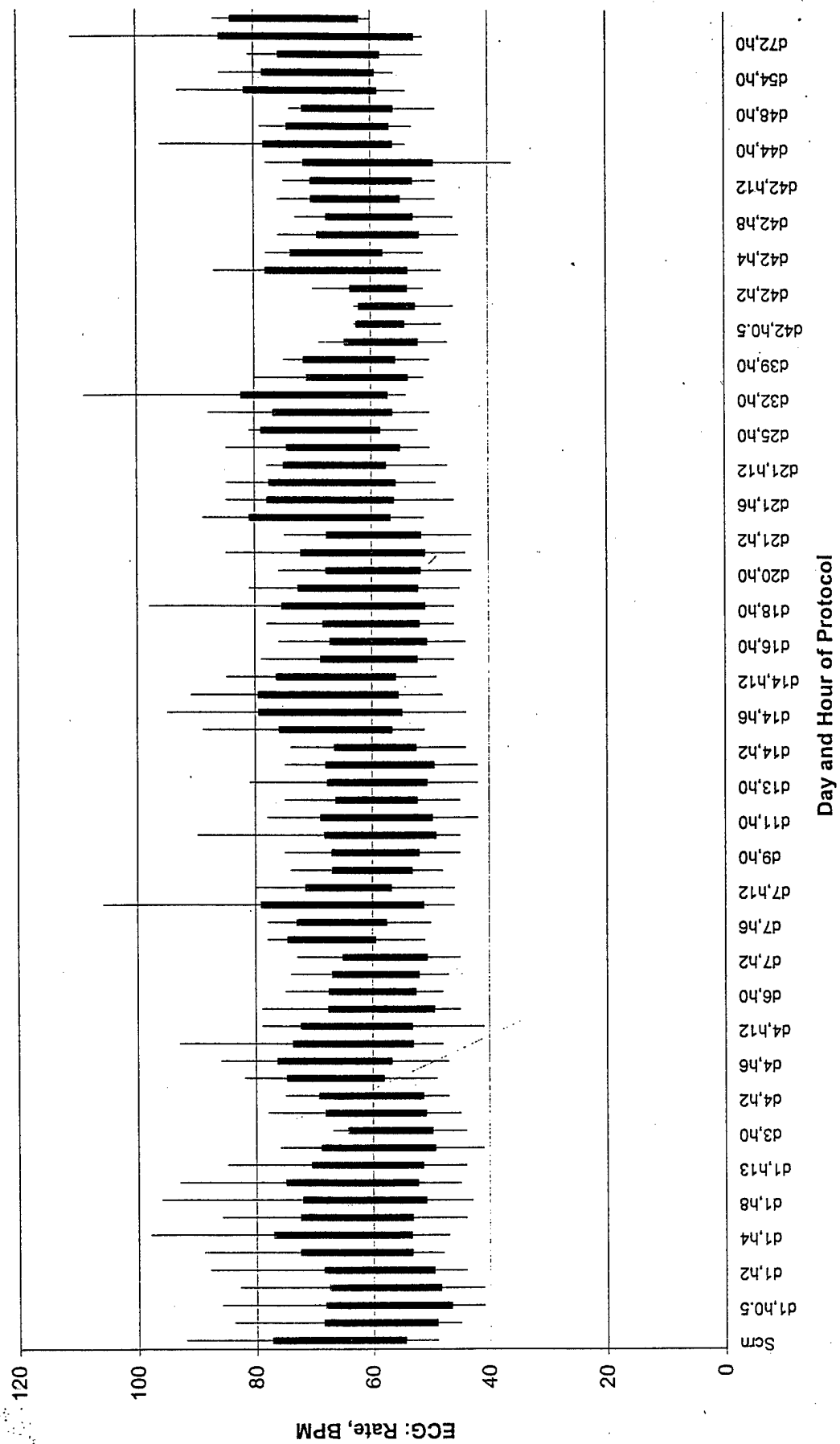
Units: BPM

Table 12a-6  
ECG: Rate

Blank = Not Obtained

Subj	Day 72 AM	Day 180 AM
01	74	84
02		
03	62	60
04		
05		
06	66	83
07	67	67
08		
09	51	62
10		
11		
12	64	69
13	59	62
14		
15	111	87
16	74	83
17		
18	90	
19	58	
20	55	
21		
Summary:		
Average	69	73
Std Dev	17	11
Max	111	87
Min	51	60

Figure 51: SD & Range Charts for ECG: Rate, BPM



Units: msec

Table 12b-1  
ECG - PR Interval

Blank = Not Obtained

Subj	Scrn	Day 1 Pre	Day 1 .5hr	Day 1 1hr	Day 1 2hr	Day 1 3hr	Day 1 4hr	Day 1 6hr	Day 1 8hr	Day 1 10hr	Day 1 12hr	Day 2 Pre	Day 3 Pre	Day 4 Pre	Day 4 2hr	Day 4 4hr	Day 4 6hr	Day 4 8hr
01	146	138	148	136	156	154	154	136	148	148	142	150	160	170	162	158	146	156
02	162	162	164	170	168	172	174	166	156	156	168	158	160	152	152	150	152	142
03	174	162	166	174	154	164	172	172	170	184	184	170	180	196	198		186	176
04	162	156	160	164	162	148	156	160	150	152	156	156	158	158	162	162	168	154
05	150	160	160	156	150	154	156	148	144	154	160	156	170	166	162	144	150	154
06	136	142	154	144	146	154	130	124	148	140	136	142	150	136	144	142	140	142
07	160	148	154	150	134	130	146	158	152	164	158	164	156	154	160	150	156	150
08	146	150	136	134	128	150	144	136	128	134	120	158	158	162	144	130	138	138
09	168	170	168	168	160		148	148	154	150	154	162	168	166	160	142	148	152
10	140	144	140	142	142	132	126	132	124	130	138	144	148	114	140	130	143	140
11	136	130	128	132	132	130	128	130	126	128	128	130	136	136	146	140	138	140
12	164	164	172	164	162	156	156	166	164	164	170	166	138	176	168	166	166	170
13	150	152	154	156	150	138	146	142	144	142	144	160	164	164	154	148	140	148
14	170	170	172	178	180	170	168	174	180	168	174	166	176	182	180	174	164	176
15	150	146	152	148	148	126	138	146	148	116	150	146	152	150	148	146	148	150
16	174	182	172	180	178	180	178	178	164	180	174	178	182	178	184	176	180	174
17	174	178	176	194	176	172	160	160										
18	140	142	142	142	144	140	138	130	140	136	140	154	152	154	146	142	142	144
19	126	136	136	134	134	130	132	134	128	132	128	138	130	136	132	128	124	130
20		142	146	142	154	146	136	138	138	142	138	140	148	144	150	148	140	152
21	154	180	152	156	170	170	160	156	160	172	162	158	148	164	160	158	152	162
Summary:	ECG - PR Interval																	
Average	154	155	155	155	154	151	150	149	148	150	151	155	157	158	158	149	151	153
Std Dev	14	15	14	17	15	17	16	16	15	18	18	12	14	19	16	14	15	13
Max	174	182	176	194	180	180	178	178	180	184	184	178	182	196	198	176	186	176
Min	126	130	128	132	128	126	126	124	124	116	120	130	130	114	132	128	124	130

Blank = Not Obtained

Table 12b-2  
ECG - PR Interval

Units: msec

Subj	Day 4 12hr	Day 5 PRE	Day 5 Pre	Day 6 Pre	Day 6 Pre	Day 7 Pre	Day 7 2hr	Day 7 4hr	Day 7 6hr	Day 7 8hr	Day 7 12hr	Day 8 Pre	Day 9 Pre	Day 10 Pre	Day 11 Pre	Day 12 Pre	Day 13 Pre	Day 14 Pre	Day 14 2hr
01	158	160	154	164	160	142	154	158	152	138	150	166	152	164	166	162	166	162	146
02	158	162	140	140	162	166	152	140	156	154	160	150	162	168	162	146	162	146	168
03	198	178	148	186	182	182	166	166	186	164	176	184	180	166	160	172	160	172	156
04	154	154	156	150	150	152	150	144	150	148	140	144	164	155	152	150	152	150	148
05	152	158	164	154	158	156	142	148	156	160	152	160	164	154	158	168	158	168	154
06	140	142	136	144	134	134	136	116	142	156	144	144	136	138	134	134	134	134	128
07	156	158	156	156	164	148	146	148	132	160	132	152	154	132	134	146	134	146	140
08	146	140	166	156	152	130	146	152	144	150	138	150							
09	158	168	174	168	150	152	156	154	154	162	162	174	174	174	136	166	168	166	158
10	134	118	140	140	142	134	138	142	136	128	146	140	134	136	134	136	148	136	140
11	144	150	146	142	140	134	132	134	136	142	146	142	146	138	152	140	152	140	148
12	176	168	178	184	178	174	164	168	170	170	178	178	176	174	176	178	176	178	184
13	144	160	156	156	150	146	140	146	148	162	160	156	136	164	162	156	162	156	148
14	182	176	180	176	178	160	166	174	172	164	158	166	162	176	182	182	182	182	184
15	152	146	150	152	148	138	140	144	152	152	154	152	158	154	158	156	154	156	154
16	188	182	184	174	190	180	174	192	172	192	184	192	196	184	196	186	186	198	192
17																			
18	152	150	160	154	154	138	136	140	146	154	154	156	152	158	152	158	156	162	154
19	128	136	134	136		126	126	130	130	138	134	136	134	136	134	130	136	136	
20	132	152	142	138	136	140	130	136	140	146	146	148	98	148	98	148	142	142	146
21	150	154	176	168	170	156	156	146	153	158	166	170	174	166	174	166	172	158	174
Summary:																			
Average	155	156	157	157	158	149	148	149	151	155	154	158	155	157	155	157	158	157	157
Std Dev	18	15	15	15	16	16	13	17	15	14	14	15	22	16	22	15	15	17	17
Max	198	182	184	186	190	182	174	192	186	192	184	192	196	184	196	184	186	198	192
Min	128	118	134	136	134	126	126	116	130	128	132	136	98	130	98	130	134	134	128

Units: msec

Table 12b-3  
ECG - PR Interval

Blank = Not Obtained

Subj	Day 14 4hr	Day 14 6hr	Day 14 8hr	Day 14 12hr	Day 15 Pre	Day 16 Pre	Day 17 Pre	Day 18 Pre	Day 19 Pre	Day 20 Pre	Day 21 Pre	Day 21 2hr	Day 21 4hr	Day 21 6hr	Day 21 8hr
01	150	136	150	140	142	148	148	156	146	158	164	160	148	144	150
02	152	158	152	156	168	166	176	180	168	172	170	176	166	188	170
03	142	158	178	180	176	162	156	176	190	170	156	154	176	176	176
04	142	144	146	154	150	142	156	150	144	146	144	150	148	140	148
05	144	146	154	170	166	156	150	140	150	162	154	146	150	144	150
06	142	136	142	148	152	136	150	144	136	132	136	146	140	138	138
07	154	158	150	136	140	156	126	152	136	144	150	152	154	152	160
08															
09	148	162	164	162	172	174	174	172	172	174	168	168	164	160	152
10	142	146	142	148	148	146	150	150	150	140	150	146	138	138	140
11	130	132		130	148	146	144	148	148	144	138	138	126	136	138
12	170	170	178	140	170	178	166	186	186	174	178	174	170	166	176
13	140	144	142	144	164	162	140	154	160	140	162	134	150	154	144
14	162	162	162	174	176	174	166	174	168	170	166	158	158	164	174
15	152	144	150	144	152	144	148	156	154	150	158	156	148	140	150
16	184	182	100	186	184	184	186	186	188	184	184	186	178	180	182
17															
18	136	132	136	144	154	152	156	156	156	160	156	146	142	140	140
19					132	136	132	140	136	136	138	126	130	128	136
20	144	136	134	130	148	146	150	144	146	144	146	146	140	134	134
21	172	154	170	168	164	180	176	166	184	186	176	176	166	156	172
Summary:															
Average	150	150	150	153	158	157	155	159	159	157	158	155	152	151	154
Std Dev	14	14	19	17	14	15	16	15	18	17	14	16	15	17	16
Max	184	182	178	186	184	184	186	186	190	186	184	186	178	188	182
Min	130	132	100	130	132	136	126	140	136	132	136	126	126	128	134

Units: msec

Table 12b-4  
ECG - PR Interval

Blank = Not Obtained

Subj	Day 21 12hr	Day 22 Pre	Day 22 Pre	Day 25 Pre	Day 29 Pre	Day 32 Pre	Day 36 Pre	Day 39 Pre	Day 42 Pre	Day 42 .5hr	Day 42 1hr	Day 42 2hr	Day 42 3hr	Day 42 4hr	Day 42 6hr	Day 42 8hr
01	148	160	172	172	148	146	148	144	148	158	138	136	144	144	146	142
02	166	172	202	202	180	176	152	158								
03	164	166	160	160	170	176	178	144	156	162	166	160	138	164	162	164
04	148	142	152	152	134	150	146									
05	154	154	152	152												
06	142	146	150	150	140	140	144	124	140	128	140	136	140	136	128	120
07	156	150	156	156	162	164	166	164	166	162	172	170	166	172	166	156
08																
09	162	168	152	152	158	164	146	154	168	160	150	146	144	150	144	148
10	128	150	142	142	134	128	140	138	138	140	148	144	142	144	150	136
11	138	136	132	132	134	134		130	136	144	144	136	132	134	138	142
12	172	168	162	162	160	162	170	158	182	178	178	182	182	178	176	174
13	148	164	152	152	134	154	158	154	164	160	158	160	166	168	160	162
14	164	172	166	166	180	164	158	162								
15	142	150	144	144	138	146	140	146	148	146	152	158	148	142	146	164
16	182	186	176	176	180	178	174	176	184	180	162	154	188	156	168	170
17																
18	148	152	134	134	140	142			140	138	142	138	136	136	130	134
19	134	134	126	126	134	144	128	126	126	126	130	126	120	128	116	122
20	138	142	140	140	140	148	140	136	152	144	148	150	148	144	142	140
21	160	188	156	156	146	154	148	148	178	172	174	162	170	146	160	156
Summary:																
Average	152	158	154	154	151	154	152	148	155	153	153	151	151	149	149	149
Std Dev	14	16	17	17	17	15	14	15	18	17	14	15	19	15	17	17
Max	182	188	202	202	180	178	178	176	184	180	178	182	188	178	176	174
Min	128	134	126	126	134	128	128	124	126	126	130	126	120	128	116	120

Units: msec

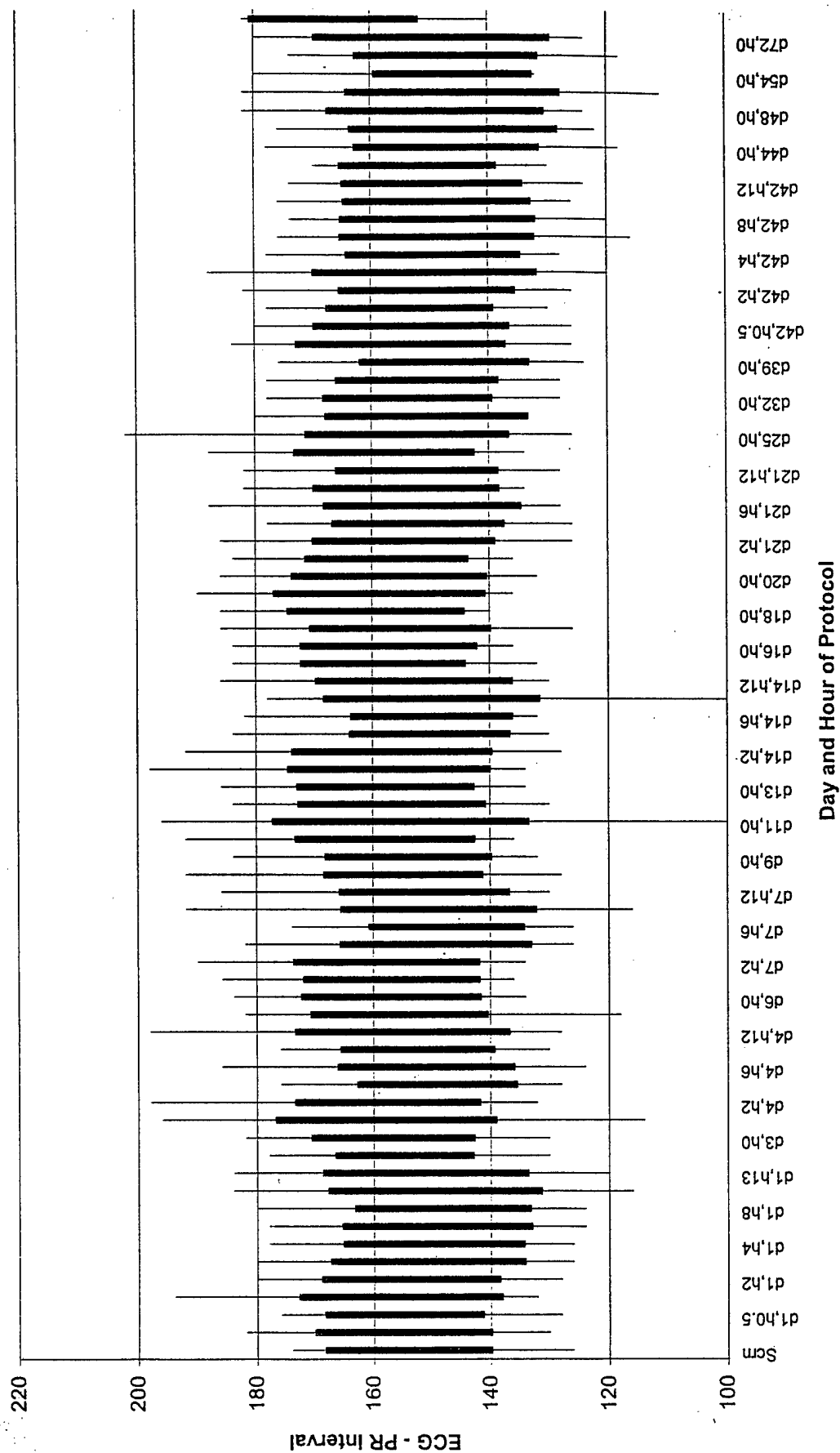
Table 12b-5  
ECG - PR Interval

Blank = Not Obtained

Subj	Day 42 10hr	Day 42 12hr	Day 43 AM	Day 44 AM	Day 45 AM	Day 48 AM	Day 51 AM	Day 54 AM	Day 57 AM	Day 72 AM	Day 180 AM
01	152	154	148	148	154	146	150	158	160	160	160
02											
03	164	162	150	158	176	162	154	136	174		178
04											
05											
06	128	124	130	134	122	124	111	138	146	128	
07	162	164	170		168	182	182	154	130	170	182
08											
09	148	156	166	162		158	142	154	152	172	158
10	126	148	146	148	130	136	140	152			
11	144	128	146	138	128						
12	176	174	170	166	174	176	168	180	166	166	172
13	164	162	160	152	152	126	148	142	154	140	
14											
15	152	148	146	144	146	148	142	138	148	140	140
16	170	170	170	178						180	174
17											
18	132	136	140	126	132		138	132	146	132	
19	128	130	130	118	136	130	124	132	118	124	
20	140	148	148	142	138	146	138	146	138	134	
21	146	140	160	146	142	154	162	136	134		
Summary:											
Average	149	150	152	147	146	149	146	146	147	150	166
Std Dev	16	16	14	16	18	19	18	14	16	20	15
Max	176	174	170	178	176	182	182	180	174	180	182
Min	126	124	130	118	122	124	111	132	118	124	140



Figure 52: SD & Range Charts for ECG - PR Interval



Units: msec

Table 12c-1  
ECG - QRS Interval

Blank = Not Obtained

Subj	Scrn	Day 1 Pre	Day 1 .5hr	Day 1 1hr	Day 1 2hr	Day 1 3hr	Day 1 4hr	Day 1 6hr	Day 1 8hr	Day 1 10hr	Day 1 12hr	Day 2 Pre	Day 3 Pre	Day 4 Pre	Day 4 2hr
01	80	86	78	82	82	80	80	82	80	78	78	82	86	80	82
02	86	84	82	92	86	72	86	82	82	86	80	84	68	74	76
03	86	84	86	86	84	86	86	84	86	84	86	82	86	88	92
04	88	84	90	90	90	82	90	88	90	92	84	90	94	96	98
05	88	80	86	90	82	84	86	78	86	84	86	88	86	84	80
06	106	106	102	104	104	108	108	110	106	108	106	104	108	104	106
07	108	106	110	108	100	104	98	104	110	108	110	102	108	102	102
08	74	86	86	88	94	74	78	72	70	86	80	82	90	86	74
09	100	100	100	96	98		94	98	94	90	94	98	98	98	94
10	74	72	70	70	72	70	72	72	68	70	72	72	70	74	74
11	86	80	78	80	78	86	84	84	84	76	78	78	84	82	80
12	88	92	100	94	100	88	90	90	84	86	92	98	94	104	98
13	92	84	98	94	94	90	92	88	88	90	88	100	100	92	92
14	108	100	100	102	98	100	90	100	110	102	102	100	100	84	100
15	102	104	104	104	100	100	104	94	102	96	102	110	98	104	102
16	84	82	80	82	86	84	84	90	88	86	88	82	94	86	84
17	84	88	88	94	94	96	96	96							
18	86	90	88	86	90	90	86	90	86	88	88	90	94	90	90
19	92	82	88	86	84	84	84	84	76	78	88	80	82	76	68
20		100	108	92	94	94	98	88	90	90	88	100	86	94	106
21	96	102	104	104	104	102	104	100	102	100	100	100	108	100	98
Summary	ECG - QRS Interval, msec														
Average	90	90	92	92	91	89	90	89	89	89	90	91	92	90	90
Std Dev	10	10	11	09	09	11	09	10	12	10	10	11	11	10	12
Max	108	106	110	108	104	108	108	110	110	108	110	110	108	104	106
Min	74	72	70	70	72	70	72	72	68	70	72	72	68	74	68

Units: msec

Table 12c-2  
ECG- QRS Interval

Blank = Not Obtained

Subj	Day 4 4hr	Day 4 6hr	Day 4 8hr	Day 4 12hr	Day 5 PRE	Day 6 Pre	Day 7 Pre	Day 7 2hr	Day 7 4hr	Day 7 6hr	Day 7 8hr	Day 7 12hr	Day 8 Pre	Day 9 Pre	Day 10 Pre
01	82	80	80	82	82	82	78	82	80	80	96	84	84	80	84
02	78	70	74	72	68	84	74	76	82	86	86	86	94	80	72
03	90	90	90	84	84	78	86	84	88	86	84	86	84	82	80
04	96	92	92	92	92	96	90	90	92	94	90	78	92	84	92
05	74	82	80	82	78	86	78	86	86	84	74	88	82	78	78
06	106	106	106	108	110	110	110	108	104	108	106	110	106	106	110
07	102	100	104	98	98	96	110	110	110	114	110	108	98	110	106
08	90	86	84	76	84	86	86	86	90	84	80	84	70	84	82
09	96	94	94	90	98	100	100	96	94	96	94	98	100	106	100
10	74	72	76	72	76	74	74	74	74	72	74	74	74	74	74
11	80	82	84	84	84	84	78	78	76	82	80	84	76	76	84
12	100	90	86	90	92	90	100	88	86	96	88	100	86	88	90
13	88	96	88	88	92	88	94	88	88	86	88	86	94	98	96
14	100	94	100	100	102	100	88	104	90	100	90	100	92	88	92
15	104	102	100	100	96	102	98	102	98	100	98	104	104	104	104
16	86	84	86	80	86	94	90	88	88	86	66	80	88	88	88
17															
18	88	86	90	92	92	92	90	90	86	98	86	90	94	94	102
19	78	76	74	78	86	70	80		84	82	86	80	82	84	92
20	94	94	104	94	102	104	100	94	92	94	96	82	108	102	102
21	100	98	96	98	100	100	104	102	98	102	100	104	108	108	102
Summary															
Average	90	89	89	88	90	91	90	91	89	92	89	90	91	91	92
Std Dev	10	10	10	10	10	10	11	11	09	10	11	11	11	12	11
Max	106	106	106	108	110	110	110	110	110	114	110	110	108	110	110
Min	74	70	74	72	68	70	74	74	74	72	66	74	70	74	72

Units: msec

Table 12c-3  
ECG-QRS Interval

Blank = Not Obtained

Subj	Day 11 Pre	Day 12 Pre	Day 13 Pre	Day 14 Pre	Day 14 2hr	Day 14 4hr	Day 14 6hr	Day 14 8hr	Day 14 12hr	Day 15 Pre	Day 16 Pre	Day 17 Pre	Day 18 Pre
01	84	84	88	84	86	98	86	96	86	84	82	86	84
02	82	72	86	82	86	86	86	86	88	78	86	70	82
03	76	84	84	86	84	78	84	86	86	80	78	78	84
04	92	82	90	80	80	92	92	80	80	76	92	86	90
05	88	78	78	70	82	76	80	76	76	80	74	78	92
06	106	106	106	100	104	104	106	102	108	104	106	106	108
07	106	98	94	106	108	108	108	112	110	106	106	106	96
08													
09	100	102	102	102	96	90	92	96	96	98	98	98	104
10	74	74	74	76	76	76	74	74	74	74	74	74	74
11	78	74	84	82	84	82	82	78	76	82	84	84	82
12	94	88	96	92	96	96	94	92	76	92	94	102	92
13	98	96	92	102	98	92	94	86	94	96	98	94	96
14	100	92	100	90	100	90	102	98	102	84	102	92	102
15	104	104	106	102	100	106	104	102	108	102	106	104	102
16	88	90	84	90	90	90	86	88	84	88	84	88	86
17													
18	92	90	92	94	92	92	86	86	90	94	94	94	90
19	86	84	74	72						76	80	74	86
20	108	78	80	102	82	86	98	102	88	90	78	100	94
21	98	102	98	100	102	100	98	98	96	100	104	106	102
Summary													
Average	92	88	90	90	91	91	92	91	90	89	91	91	92
Std Dev	11	11	10	11	09	10	10	10	12	10	11	12	09
Max	108	106	106	106	108	108	108	112	110	106	106	106	108
Min	74	72	74	70	76	76	74	74	74	74	74	70	74

Units: msec

Table 12c-4  
ECG- QRS Interval

Blank = Not Obtained

Subj	Day 19 Pre	Day 20 Pre	Day 21 Pre	Day 21 2hr	Day 21 4hr	Day 21 6hr	Day 21 8hr	Day 21 12hr	Day 22 Pre	Day 25 Pre	Day 29 Pre	Day 32 Pre	Day 36 Pre
01	76	84	82	82	86	84	84	82	84	80	88	84	84
02	70	84	88	72	82	92	86	84	88	70	80		90
03	80	84	82	90	82	90	82	82	82	82	88	86	86
04	90	88	90	90	92	82	96	98	80	90	90	90	88
05	86	78	78	76	74	74	76	76	80	80			
06	106	108	106	106	110	106	104	108	106	104	106	108	106
07	98	100	96	98	102	96	102	100	106	104	106	110	106
08													
09	102	102	96	98	96	98	96	90	98	100	94	96	102
10	74	72	74	72	72	74	72	72	72	72	74	74	74
11	84	84	86	82	80	80	80	74	80	86	76	86	
12	88	96	82	96	88	84	90	90	90	82	86	94	88
13	94	100	102	84	86	86	88	86	94	88	104	92	96
14	90	100	88	100	92	100	92	84	92	98	90	106	100
15	104	106	102	104	102	100	102	100	106	104	102	100	104
16	88	90	86	84	88	84	82	88	86	84	86	92	84
17													
18	92	92	92	94	90	86	88	94	94	90	84	94	
19	84	90	76	74	80	80	72	80	74	88	76	80	88
20	102	96	76	102	96	96	92	92	80	94	94	90	86
21	108	106	100	104	100	100	100	100	102	102	102	106	90
Summary													
Average	90	93	89	90	89	89	89	88	89	89	90	93	92
Std Dev	11	10	10	11	10	09	10	10	11	11	10	10	09
Max	108	108	106	106	110	106	104	108	106	104	106	110	106
Min	70	72	74	72	72	74	72	72	72	70	74	74	74

Units: msec

Table 12c-5  
ECG-QRS Interval

Blank = Not Obtained

Subj	Day 39 Pre	Day 42 Pre	Day 42 .5hr	Day 42 1hr	Day 42 2hr	Day 42 3hr	Day 42 4hr	Day 42 6hr	Day 42 8hr	Day 42 10hr	Day 42 12hr	Day 43 AM	Day 44 AM
01	82	94	94	88	78	82	80	82	84	80	84	100	86
02	90												
03	84	86	84	82	86	82	84	94	82	86	84	84	92
04													
05													
06	108	106	104	106	106	106	104	112	112	112	114	108	108
07	110	112	112	112	114	114	116	114	110	116	112	112	
08													
09	98	100	90	98	90	92	96	86	94	96	98	102	94
10	74	72	74	72	82	72	74	72	70	74	72	74	74
11	84	84	84	84	78	84	76	86	86	82	78	76	76
12	96	88	90	86	88	92	92	86	86	92	88	92	96
13	98	96	108	100	90	94	94	100	100	88	90	92	94
14	84												
15	104	100	96	100	106	104	108	100	104	96	104	108	102
16	84	90	88	78	86	74	82	84	78	86	80	84	84
17													
18		94	92	90	94	94	94	84	90	88	84	92	98
19	78	80	72	80	72	82	78	74	78	74	74	78	80
20	96	84	86	80	86	86	86	86	84	82	86	84	86
21	96	108	106	106	106	102	108	104	106	106	104	104	106
Summary													
Average	92	93	92	91	91	91	91	91	91	91	90	93	91
Std Dev	11	11	12	12	12	12	13	13	13	13	13	12	11
Max	110	112	112	112	114	114	116	114	112	116	114	112	108
Min	74	72	72	72	72	72	74	72	70	74	72	74	74

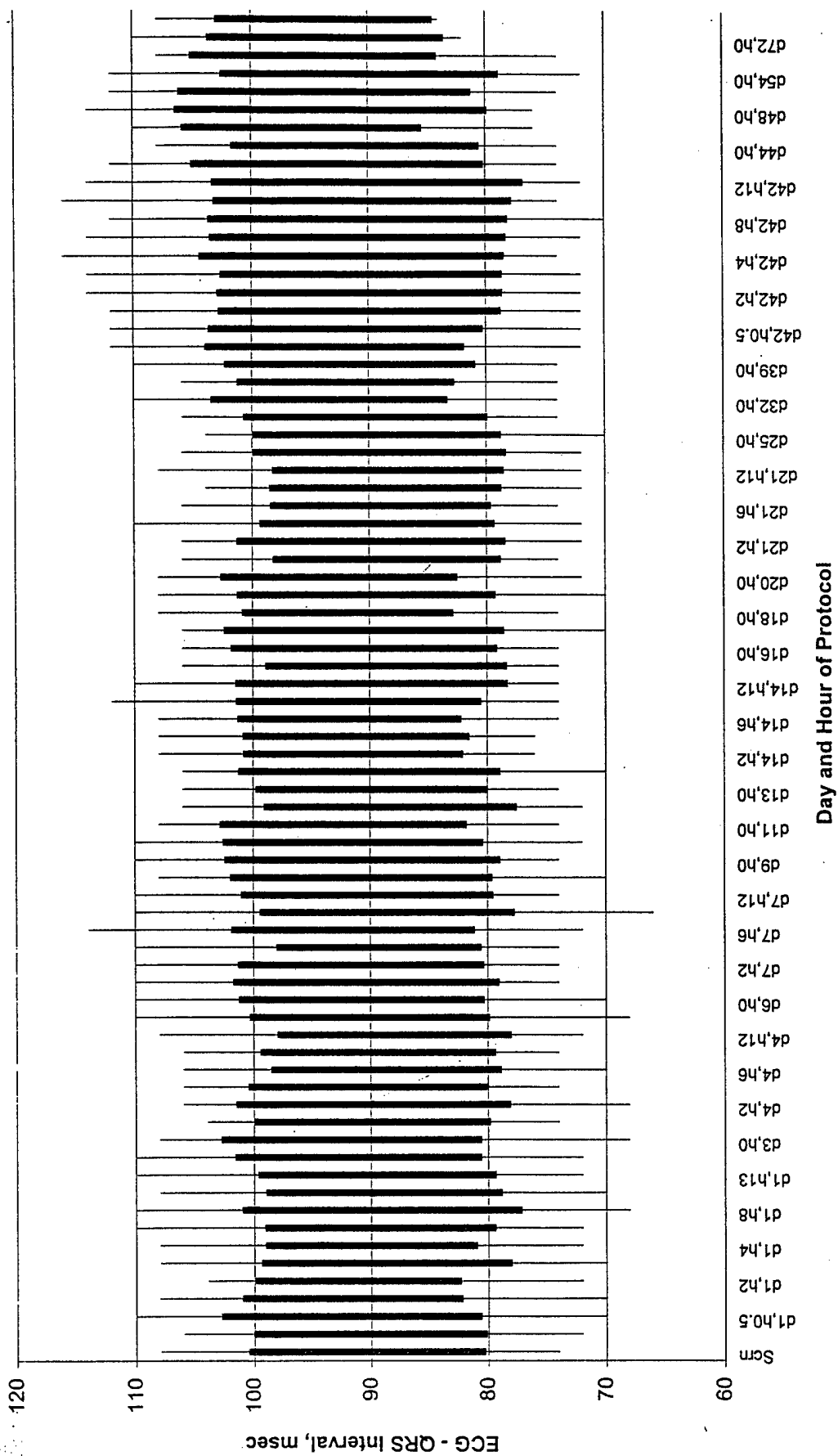
Units: msec

Table 12c-6  
ECG-QRS Interval

Blank = Not Obtained

Subj	Day 45 AM	Day 48 AM	Day 51 AM	Day 54 AM	Day 57 AM	Day 72 AM	Day 180 AM
01	92	80	84	84	86	98	84
02							
03	94	80	82	80	86		86
04							
05							
06	110	114	110	112	106	110	104
07	108	108	112	108	106	108	108
08							
09		94	102	94	96	94	90
10		76	74	72			
11	84						
12	92	86	88	86	88	88	90
13	92	90	90	88	88	96	94
14							
15	104	104	102	98	100	102	104
16						84	84
17							
18	92		94	92	94	86	
19	76	78	80	74	74	82	
20	96	102	90	96	108	82	
21	108	106	110	96	104		
Summary							
Average	96	93	94	91	95	94	94
Std Dev	10	13	12	12	11	10	09
Max	110	114	112	112	108	110	108
Min	76	76	74	72	74	82	84

Figure 53: SD & Range Charts for ECG - QRS Interval, msec





Units: msec

Table 12d-1  
ECG-QTc Interval

Blank = Not Obtained

Subj	Scrn	Day 1 Pre	Day 1 .5hr	Day 1 1hr	Day 1 2hr	Day 1 3hr	Day 1 4hr	Day 1 6hr	Day 1 8hr	Day 1 10hr	Day 1 12hr	Day 2 Pre	Day 3 Pre	Day 4 Pre	Day 4 2hr
01	397	399	397	403	384	371	407	396	393	402	391	381	392	389	386
02	413	404	409	405	387	419	410	382	442	411	414	399	408	393	413
03	380	402	379	375	410	412	401	403	406	392	384	388	393	392	407
04	406	383	389	373	376	398	395	395	396	389	397	388	401	411	423
05	372	390	376	394	407	372	373	387	383	404	404	388	383	403	397
06	385	382	368	356	347	369	363	345	353	386	358	341	348	352	348
07	412	398	378	403	420	409	408	364	368	396	406	388	391	410	388
08	383	372	371	380	380	366	371	401	383	379	383	383	384	377	372
09	379	395	374	375	359		386	401	391	381	391	368	393	416	384
10	400	398	392	400	402	409	399	395	396	406	400	377	404	404	413
11	418	412	421	414	409	455	474	414	414	415	416	423	444	435	425
12	394	384	376	399	387	399	396	367	389	378	364	379	390	360	363
13	394	383	397	395	390	394	390	392	393	389	389	391	373	377	395
14	408	403	406	399	421	416	389	385	426	419	426	420	403	408	412
15	389	401	388	349	395	374	395	397	392	388	388	399	405	381	416
16	399	380	396	393	390	400	400	394	374	400	400	392	382	399	395
17	409	360	409	341	349	346	359	346							
18	417	403	394	400	409	403	403	402	403	409	402	409	411	416	412
19	418	395	377	366	389	404	418	402	402	405	404	402	422	410	404
20		422	392	415	404	402	402	398	398	392	402	438	383	397	422
21	401	406	403	412	408	409	423	405	406	408	409	408	409	418	422
Summary	ECG - QTc Interval, msec														
Average	399	394	390	388	392	396	398	389	395	397	396	393	396	397	400
Std Dev	14	14	14	21	21	24	24	19	19	12	16	21	20	20	21
Max	418	422	421	415	421	455	474	414	442	419	426	438	444	435	425
Min	372	360	368	341	347	346	359	345	353	378	358	341	348	352	348

Units: msec

Table 12d-2  
ECG-QTc Interval

Blank = Not Obtained

Subj	Day 4 4hr	Day 4 6hr	Day 4 8hr	Day 4 12hr	Day 5 PRE	Day 6 Pre	Day 7 Pre	Day 7 2hr	Day 7 4hr	Day 7 6hr	Day 7 8hr	Day 7 12hr	Day 8 Pre	Day 9 Pre	Day 10 Pre
01	398	409	382	399	375	393	369	411	402	399	389	403	405	398	403
02	408	417	413	413	406	412	409	401	408	419	507	420	425	419	406
03	406	400	404	402	380	390	401	414	403	404	404	407	401	383	404
04	398	398	417	404	399	411	406	398	402	396	400	402	398	400	398
05	381	410	402	391	382	415	411	374	395	399	369	413	400	389	396
06	379	371	385	385	349	357	391	355	374	388	387	382	390	356	364
07	423	414	413	417	403	410	414	398	435	419	411	453	418	418	414
08	388	404	382	407	385	385	387	398	409	394	398	384	402	417	390
09	403	391	385	409	384	397	372	358	389	407	396	406	399	428	411
10	412	405	412	414	412	409	410	419	405	399	418	406	414	414	438
11	437	416	448	439	439	444	421	434	424	429	437	410	424	423	430
12	391	393	382	361	396	356	382	399	391	394	378	392	394	400	403
13	394	402	380	394	384	409	407	403	396	374	401	399	411	394	396
14	410	403	407	398	404	419	412	413	416	412	420	420	413	413	424
15	396	383	401	381	388	404	398	383	395	365	394	371	397	396	401
16	396	399	401	401	403	404	405	404	401	400	399	407	406	405	400
17															
18	413	441	411	415	422	415	421	410	438	435	422	421	418	451	422
19	409	410	418	404	404	404	403		403	413	421	408	403	409	406
20	404	403	413	416	378	411	407	411	413	408	400	405	411	407	413
21	404	420	402	406	411	404	417	411	420	408	421	426	409	416	407
Summary															
Average	403	404	403	403	395	402	402	400	406	403	409	407	407	407	406
Std Dev	14	15	17	16	20	20	15	20	15	17	28	18	10	19	16
Max	437	441	448	439	439	444	421	434	438	435	507	453	425	451	438
Min	379	371	380	361	349	356	369	355	374	365	369	371	390	356	364

Units: msec

Table 12d-3  
ECG-QTc Interval

Blank = Not Obtained

Subj	Day 11 Pre	Day 12 Pre	Day 13 Pre	Day 14 Pre	Day 14 2hr	Day 14 4hr	Day 14 6hr	Day 14 8hr	Day 14 12hr	Day 15 Pre	Day 16 Pre	Day 17 Pre	Day 18 Pre
01	389	389	404	396	404	404	402	406	404	372	393	385	401
02	428	433	418	413	464	416	450	422	452	434	422	411	428
03	405	402	388	405	402	382	403	403	408	386	410	399	410
04	401	400	400	401	402	398	404	399	402	399	402	396	403
05	405	403	416	417	395	396	409	370	401	391	387	394	416
06	360	359	359	346	350	382	374	389	381	377	387	369	388
07	401	423	412	408	407	446	440	485	424	408	418	403	411
08													
09	391	413	423	398	412	406	393	411	417	383	407	403	416
10	420	418	406	402	406	442	439	450	420	414	426	411	431
11	427	412	407	438	409	447	436	439	452	448	446	424	437
12	404	401	401	394	392	375	401	391	396	395	399	369	397
13	379	403	391	389	398	408	371	438	410	403	407	395	417
14	428	421	418	413	419	413	413	405	417	407	412	422	401
15	404	388	401	396	398	430	410	409	398	400	385	375	403
16	408	397	411	402	416	403	404	403	400	399	402	412	396
17													
18	416	419	440	430	425	428	425	420	428	426	437	424	431
19	407	408	393	416						403	399	415	405
20	409	425	415	411	405	410	410	426	424	409	417	411	411
21	416	419	409	400	411	406	416	403	410	415	419	405	412
Summary													
Average	405	407	406	404	406	411	411	415	414	404	409	401	411
Std Dev	17	17	17	19	21	21	21	26	18	19	17	17	13
Max	428	433	440	438	464	447	450	485	452	448	446	424	437
Min	360	359	359	346	350	375	371	370	381	372	385	369	388

Units: msec

Table 12d-4  
ECG-QTc Interval

Blank = Not Obtained

Subj	Day 19 Pre	Day 20 Pre	Day 21 Pre	Day 21 2hr	Day 21 4hr	Day 21 6hr	Day 21 8hr	Day 21 12hr	Day 22 Pre	Day 25 Pre	Day 29 Pre	Day 32 Pre	Day 36 Pre
01	427	404	400	396	409	400	421	402	423	416	450	449	407
02	434	432	428	393	419	466	505	450	455	462	432	479	441
03	408	389	409	387	390	409	406	418	404	405	408	412	389
04	399	402	402	402	409	406	411	408	427	420	414	404	402
05	407	400	390	385	403	380	415	389	395	395			
06	380	368	360	394	393	389	391	388	382	396	390	394	370
07	420	412	440	432	423	420	432	431	424	481	440	456	405
08													
09	374	421	368	427	427	440	433	416	438	438	410	409	432
10	440	420	415	403	433	451	429	446	416	405	432	414	377
11	431	458	451	454	441	450	483	438	440	474	441	438	
12	393	390	382	390	400	395	393	399	393	402	401	406	405
13	389	374	377	393	405	395	399	398	394	420	420	412	409
14	422	421	421	415	413	420	414	421	416	444	450	430	448
15	409	397	392	401	435	416	409	403	394	423	418	402	407
16	403	411	404	391	421	414	410	411	400	420	426	434	424
17													
18	452	432	426	414	437	446	428	428	431	450	426	453	
19	411	408	396	404	407	405	405	405	410	408	411	442	420
20	402	409	410	411	417	417	432	416	424	415	448	426	427
21	426	413	411	406	407	397	407	429	409	409	413	415	417
Summary													
Average	412	408	404	405	415	417	422	416	414	425	424	426	411
Std Dev	21	21	24	17	15	24	29	18	19	26	17	23	21
Max	452	458	451	454	441	466	505	450	455	481	450	479	448
Min	374	368	360	385	390	380	391	388	382	395	390	394	370

Units: msec

Table 12d-5  
ECG-QTc Interval

Blank = Not Obtained

Subj	Day 39 Pre	Day 42 Pre	Day 42 .5hr	Day 42 1hr	Day 42 2hr	Day 42 3hr	Day 42 4hr	Day 42 6hr	Day 42 8hr	Day 42 10hr	Day 42 12hr	Day 43 AM	Day 44 AM
01	403	407	405	406	405	456	397	369	425	398	406	407	412
02	427												
03	385	401	387	385	403	377	353	376	385	376	395	401	401
04													
05													
06	385	371	376	364	361	345	394	354	362	343	352	382	352
07	453	424	427	428	423	420	416	419	421	430	417	364	442
08													
09	419	415	470	387	391	417	413	413	419	424	420	418	413
10	414	413	373	392	379	445	436	411	410	419	418	430	415
11	452	473	434	418	451	491	476	478	471	425	450	434	427
12	408	404	408	378	398	402	405	353	369	399	404	391	411
13	409	383	408	415	411	374	390	375	375	383	395	396	422
14	438												
15	404	406	393	410	392	414	389	408	404	402	420	415	401
16	427	438	420	407	403	433	408	416	414	410	415	419	422
17													
18		475	462	456	434	464	454	420	415	426	428	423	445
19	401	440	409	398	405	416	406	403	410	403	410	406	398
20	421	438	437	425	428	442	442	435	420	416	425	414	411
21	416	415	407	411	413	420	407	405	403	408	411	401	411
Summary													
Average	416	420	414	405	406	421	412	402	407	404	411	407	412
Std Dev	20	29	28	23	22	37	30	33	27	23	21	19	21
Max	453	475	470	456	451	491	476	478	471	430	450	434	445
Min	385	371	373	364	361	345	353	353	362	343	352	364	352

Units: msec

Table 12d-6  
ECG-QTc Interval

Blank = Not Obtained

Subj	Day 45 AM	Day 48 AM	Day 51 AM	Day 54 AM	Day 57 AM	Day 72 AM	Day 180 AM
01	396	385	383	396	398	410	397
02							
03	404	403	404	385	397	401	406
04							
05							
06	337	384	389	388	385	375	402
07	432	428	444	428	424		424
08							
09		404	454	384	433	367	388
10		406	411	404			
11	463						
12	394	403	406	398	415	360	411
13	421	408	404	404	406	412	394
14							
15	395	389	399	347	383	432	397
16						399	416
17							
18	440		424	419	415	416	
19	393	406	415	367	401	403	
20	411	412	414	407	382	409	
21	422	434	410	468	411	446	
Summary							
Average	409	405	412	400	404	403	404
Std Dev	31	15	20	29	16	25	11
Max	463	434	454	468	433	446	424
Min	337	384	383	347	382	360	388

Figure 54: SD & Range Charts for ECG - QTc Interval, msec

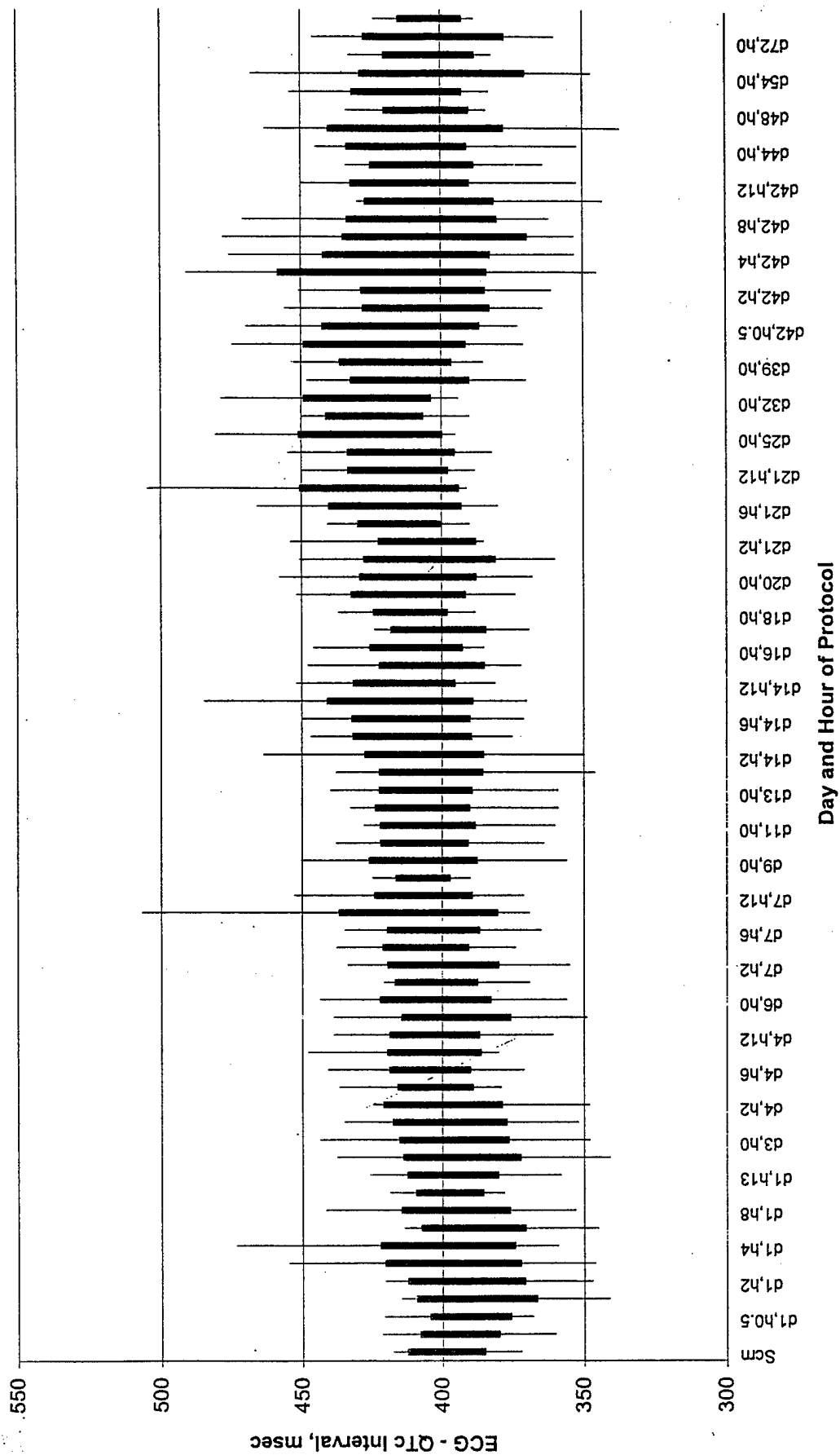


Table 13a-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 01

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	399				
1	.5HR	397				
1	1HR	403				
1	2HR	384				
1	3HR	371				16.4
1	4HR	407	10.9			20.9
1	6HR	396	15.1			18.5
1	8HR	393	15			27
1	10HR	402	17.2	10.4		27.7
1	12HR	391	12.9			22.3
2	PRE	381				23.2
3	PRE	392	10.9			29.5
4	PRE	389	32			36.4
4	2HR	386	30.6	22.8		38.4
4	4HR	398	73.2	41.7		44.3
4	6HR	409	47.9	37.7		84.7
4	8HR	382	38.9	17.1		52.4
4	12HR	399	54.6	30.7		64.7
5	PRE	375	25.9	22.5	17.2	76.2
6	PRE	393	37.9	16.5	20.8	108
7	PRE	369	43.4	18.2	26.1	128
7	2HR	411	55.8	33.7	16.8	74.1
7	4HR	402	93.4	59.3	32.6	153
7	6HR	399	131	73.1	37.2	202
7	8HR	389	144	79.6	74	203
7	12HR	403	101	50.6	56.4	149
8	PRE	405	57.6	27.4	62.7	183
9	PRE	398	77.2	33.1	72.6	221
10	PRE	403	68.9	28	87.8	282
11	PRE	389	50.6	20.4	54.2	227
12	PRE	389	51.3	20.8	45.3	325
13	PRE	404	55.9	25.4	44.1	334
14	PRE	396	58.6	25.5	29.7	311
14	2HR	404	65.6	30.3	22.8	211
14	4HR	404				
14	6HR	402	73.3	37.4	36.4	324
14	8HR	406	68.2	36.2	32.2	318
14	12HR	404	80.8	35	35	260



Table 13a-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 01

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	427	68.3	32.8	41.1	409
16	PRE	404	80.6	36.6	32.6	361
17	PRE	400	84.5	37.4	38.8	497
18	PRE	396	92.8	41	59.1	532
19	PRE	409	94.6	51.7	51	435
20	PRE	400	127	70	59.1	496
21	PRE	421	81	40.6	32.2	290
21	2HR	402	96.8	51.7	30.5	251
21	4HR	423	52.5	24.4	38.2	295
21	6HR	416	70.5	31.1	54.4	386
21	8HR	450	169	93.7	51.2	335
21	12HR	449	82.4	35.8	33.6	385
22	PRE		59.2	25.9	49	329
25	PRE	407	54.6	26.7	29.3	289
29	PRE	403	54.4	23.7	30.9	355
32	PRE	407	109	50.2	52.8	484
33	PRE	405	121	55.8	63.5	506
36	PRE	406	112	56	53	468
39	PRE	405	134	68	67	535
42	PRE	456	160	88.2	66.8	687
42	.5HR	397	157	91.4	53.8	565
42	1HR	369	181	106	59.1	576
42	2HR	425	193	110	61.1	538
42	3HR	398	153	93.7	32.6	339
42	4HR	406	168	90.5	77.7	633
42	6HR	407	64	35.2	29.7	224
42	8HR	412	67.9	27.6	39	424
42	10HR	396	46.3	18.8	37.8	508
42	12HR	385	46.7	18.4	15.8	340
43	AM	383	34.9	12.7		255
44	AM	396	29.9	10.4		175
45	AM	398	32.1	12.3		128
48	AM	410	33.8	15.2	27.7	243
51	AM	397				16.4
54	AM					
57	AM					
72	AM					
180	AM					

Table 13b-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 02

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	404				
1	.5HR	409				
1	1HR	405				
1	2HR	387				
1	3HR	419				
1	4HR	410				
1	6HR	382	31.5	22.7		
1	8HR	442	25	35.1		
1	10HR	411	29.5	20.1		
1	12HR	414	20.1	12.3		
2	PRE	399	13			
3	PRE	408				
4	PRE	393	30.4	16.5		31.5
4	2HR	413	37.7	37.1		60.6
4	4HR	408	79.1	55.5	19	61.2
4	6HR	417	63.5	38.7		63.6
4	8HR	413	46.4	26.3		34.7
4	12HR	413	33.1	18.1		53
5	PRE	406	26.9	16.6		55.8
6	PRE	412	29.7	16.6		77.7
7	PRE	409	30.3	14.8	18	84.4
7	2HR	401	31.2	19.2	16.8	71.8
7	4HR	408	78.4	53.7	29.7	121
7	6HR	419	72.8	43	17.6	78.1
7	8HR	507	67.9	41.4	23.3	91.8
7	12HR	420	48.6	25.9	29.3	100
8	PRE	425	30.3	15.7	20.2	93.8
9	PRE	419	50.7	27	23.9	101
10	PRE	406	61	27.8	31.1	140
11	PRE	428	64.4	32.7	34.3	174
12	PRE	433	69.7	33.2	36.6	174
13	PRE	418	79.8	43.4	36	194
14	PRE	413	52.8	25	32.9	161
14	2HR	464	75.5	46.7	29.7	160
14	4HR	416	83.9	51.8	36	188
14	6HR	450	107	62.5	39.8	229
14	8HR	422	123	71.9	42.8	232
14	12HR	452	84.2	46	36	201

Table 13b-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 02

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	434	104	59.8	39.4	218
16	PRE	432	125	66.4	39.6	219
17	PRE	428	83.1	40.8	33.9	193
18	PRE	393	139	99.5	36.6	209
19	PRE	419	273	240	43.4	263
20	PRE	466	369	298	52.3	274
21	PRE	505	319	239	59.7	336
21	2HR	450	263	179	62	372
21	4HR	455	127	75.4	35.6	243
21	6HR	462	108	60.4	53.3	289
21	8HR	432	195	122	48.9	292
21	12HR	479	111	60.6	74.9	432
22	PRE		65.9	31.2	57.9	431
25	PRE	441	60.8	33.2	60.8	459
29	PRE	427				
32	PRE					
33	PRE					
36	PRE					
39	PRE					
42	PRE					
42	.5HR					
42	1HR					
42	2HR					
42	3HR					
42	4HR					
42	6HR					
42	8HR					
42	10HR					
42	12HR					
43	AM					
44	AM					
45	AM					
48	AM					
51	AM					
54	AM					
57	AM					
72	AM					
180	AM					

Table 13c-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 04

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	383				
1	.5HR	389				
1	1HR	373				
1	2HR	376	16.4	12.6		
1	3HR	398	52.6	37.9		18.6
1	4HR	395	35.1	20.5		20.1
1	6HR	395	71.1	32.8	20.9	46
1	8HR	396	44.5	19	18.5	47.1
1	10HR	389	18.9			33.9
1	12HR	397	29.6	10.2		40.7
2	PRE	388	14.6		18	38
3	PRE	401	25.6	10.7	20.1	69.5
4	PRE	411	79.9	41.8	30.3	96.8
4	2HR	423	308	356	62	199
4	4HR	398	348	329	40.5	125
4	6HR	398	446	310	54.8	165
4	8HR	417	292	191	55.3	192
4	12HR	404	246	146	51.5	181
5	PRE	399	107	57.9	65.8	211
6	PRE	411	132	74.4	53.7	234
7	PRE	406	85.6	38.6	52.1	260
7	2HR	398	109	60.3	45.9	242
7	4HR	402	183	107	64.7	314
7	6HR	396	141	72.5	44.6	207
7	8HR	400	111	55.7	32.2	149
7	12HR	402	109	49.7	28.2	134
8	PRE	398	97.9	35	20.1	92.4
9	PRE	400	69.2	30	24.4	138
10	PRE	398	70.6	29.8	26.3	138
11	PRE	401	68.9	30.3	30.3	175
12	PRE	400	73.1	32.2	21.5	135
13	PRE	400	74.5	28.1	23.9	121
14	PRE	401	124	52.7	31.4	200
14	2HR	402	110	50.2	32.5	160
14	4HR	398	205	104	33	174
14	6HR	404	234	119	39.5	193
14	8HR	399	166	79.4	27.9	124
14	12HR	402	117	51.6	22.5	114

Table 13c-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 04

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	399	66.4	28.1	40.8	264
16	PRE	402	81.4	31.5	46.7	313
17	PRE	402	97.7	38.6	45.4	283
18	PRE	402	137	62.7	67.4	449
19	PRE	409	195	113	41.1	303
20	PRE	406	224	122	45.1	285
21	PRE	411	190	95.4	67.1	368
21	2HR	408	146	63.9	57.2	330
21	4HR	427	92.8	36.9	43.8	296
21	6HR	420	84	32.8	59.3	349
21	8HR	414	75.9	28.5	60.4	318
21	12HR	404	105	40.2	54	411
22	PRE					
25	PRE	402	59.1	23.5	45.4	259
29	PRE		52.2	19.2	31.4	219
32	PRE					
33	PRE					
36	PRE					
39	PRE					
42	PRE					
42	.5HR					
42	1HR					
42	2HR					
42	3HR					
42	4HR					
42	6HR					
42	8HR					
42	10HR					
42	12HR					
43	AM					
44	AM					
45	AM					
48	AM					
51	AM					
54	AM					
57	AM					
72	AM					
180	AM					

Table 13d-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 05

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	390				
1	.5HR	376				
1	1HR	394	11.4	10.7		
1	2HR	407	19.9	17.2		
1	3HR	372	19.5	15.1		15
1	4HR	373	15.1			15
1	6HR	387	34.7	18.6		29.3
1	8HR	383	20.3	10.3		18.7
1	10HR	404	37.4	16.3		47.3
1	12HR	404	14.5			18.4
2	PRE	388				29.3
3	PRE	383	14.3			54.2
4	PRE	403	20.1	13.1		46.4
4	2HR	397	22.2	15.1		40.5
4	4HR	381	78.6	44.2		88
4	6HR	410	50.2	27		70
4	8HR	402	67.3	32.6	22.4	98.6
4	12HR	391	52.6	25.5	20.7	97
5	PRE	382	26.7	11.7	28.8	118
6	PRE	415	26.1		16.2	100
7	PRE	411	27.2	11.2	17.9	136
7	2HR	374	19.4	11.4	15.6	79.3
7	4HR	395	43.3	23.9	26	175
7	6HR	399	58.7	31.8	26	199
7	8HR	369	37.8	18.6	18.7	139
7	12HR	413	31.9	14.8		83
8	PRE	400	28.4	12.3	17.9	131
9	PRE	389	33	15.4	27.4	179
10	PRE	396	35.8	14	23.2	155
11	PRE	405	27.8	11.4	22.1	161
12	PRE	403	34.8	14.9	19.8	186
13	PRE	416	35.3	16	26.6	283
14	PRE	417	51.6	26.9	32.2	304
14	2HR	395	56.4	35.1	19.8	192
14	4HR	396	116	66.5	55.4	453
14	6HR	409	74	41.3	36.1	274
14	8HR	370	67.4	35.2	29.4	235
14	12HR	401	46.4	23	29.1	198

Table 13d-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 05

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	407	50	23.1	29.1	297
16	PRE	400	39.4	18.2	30.5	331
17	PRE	390	40.5	19	39.7	340
18	PRE	385	75.1	46.2	31.9	333
19	PRE	403	79.3	41.9	32.2	312
20	PRE	380	95.3	55.1	48.4	438
21	PRE	415	62.2	32.9	31.9	260
21	2HR	389	54.3	28.7	47.3	401
21	4HR	395	35.9	16.8	24.9	246
21	6HR	395	31.3	14.8	29.4	32.1
21	8HR					
21	12HR					
22	PRE					
25	PRE					
29	PRE					
32	PRE					
33	PRE					
36	PRE					
39	PRE					
42	PRE					
42	.5HR					
42	1HR					
42	2HR					
42	3HR					
42	4HR					
42	6HR					
42	8HR					
42	10HR					
42	12HR					
43	AM					
44	AM		14.2			20.9
45	AM					
48	AM					
51	AM					
54	AM					
57	AM					
72	AM					
180	AM					

Table 13e-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 07

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	398				
1	.5HR	378				
1	1HR	403				
1	2HR	420	10.8			
1	3HR	409	14.9	10.6		
1	4HR	408	28.4	18.7		15.8
1	6HR	364	23.3	15.6		15.8
1	8HR	368	23.5	15.6		17.6
1	10HR	396	20.9	14.1		18.3
1	12HR	406	17.5	12.5		
2	PRE	388	10.3	10.6		
3	PRE	391	50.8	36.6		38.9
4	PRE	410	75.4	48.3	22.6	71.8
4	2HR	388	342	326	34.6	92.8
4	4HR	423	572	570		110
4	6HR	414	456	343	50.3	135
4	8HR	413	290	223	40.2	131
4	12HR	417	235	158	39.3	101
5	PRE	403	88.4	56.5	22.9	93.8
6	PRE	410	73.3	45	31.7	132
7	PRE	414	149	85.6	80.9	211
7	2HR	398	186	128	40.9	202
7	4HR	435	184	127	28.6	106
7	6HR	419	227	152	40.6	150
7	8HR	411	229	152	42.8	135
7	12HR	453	180	117	42.4	138
8	PRE	418	108	67.3	24.8	113
9	PRE	418	89.1	56	21.3	102
10	PRE	414	105	58.8	27	132
11	PRE	401	121	71.5	33.9	138
12	PRE	423	112	63.8	25.7	123
13	PRE	412	145	74.5	27.9	128
14	PRE	408	142	75.9	27.9	174
14	2HR	407	142	84.8	27	163
14	4HR	446	265	161	32	138
14	6HR	440	264	154	41.5	180
14	8HR	485	213	115	33	143
14	12HR	424	232	124	43.7	187



Table 13e-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 07

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	420	150	72.4	32.7	166
16	PRE	412	160	79	36.1	174
17	PRE	440	226	110	54.8	257
18	PRE	432	272	156	52.5	246
19	PRE	423	292	152	61.7	279
20	PRE	420	312	171	62	260
21	PRE	432	258	130	48.4	211
21	2HR	431	250	121	50.3	212
21	4HR	424	170	80.8	41.8	205
21	6HR	481	162	73.2	42.4	184
21	8HR	440	123	57	38.7	177
21	12HR	456	155	78	51.6	297
22	PRE		93.9	55.7	34.9	189
25	PRE	405	116	60.2	47.5	267
29	PRE	453	206	97.6	61.1	312
32	PRE	424	182	80.6	79.7	402
33	PRE	427	123	56.2	61.1	246
36	PRE	428	150	71.5	63.3	289
39	PRE	423	151	79.1	55.4	244
42	PRE	420	165	81.7	47.8	277
42	.5HR	416	204	106	59.8	382
42	1HR	419	172	83.2	47.2	350
42	2HR	421	202	95.6	63.3	408
42	3HR	430	224	92.9	56.3	335
42	4HR	417	201	88.5	53.8	353
42	6HR	364	175	72.7	60.1	382
42	8HR	442				
42	10HR	432	68.6	45.2	20.7	217
42	12HR	428				
43	AM	444	42	18.7		97.3
44	AM	428	46.6	21.1		48
45	AM	424	49.9	21.6		51.5
48	AM		29.2	23.4		17.2
51	AM	424				
54	AM					
57	AM					
72	AM					
180	AM					

Table 13f-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 08

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	372				
1	.5HR	371				
1	1HR	380	15.9	13.9		
1	2HR	380	37.6	32.9		
1	3HR	366	65.3	50.3		33.1
1	4HR	371	78.9	57.7	16.4	35.7
1	6HR	401	162	113	18.8	50.5
1	8HR	383	102	69.7	21.5	51.5
1	10HR	379	61.9	41.7		37.1
1	12HR	383	62.1	40.3		41.4
2	PRE	383	24.1	13.6		33.4
3	PRE	384	45.5	21.7		44.1
4	PRE	377	33.2	19.9	17.3	76.5
4	2HR	372	67.3	49.8	26	100
4	4HR	388	152	113	47.2	199
4	6HR	404	114	75.4	27.2	110
4	8HR	382	103	66.6	33.9	129
4	12HR	407	136	76.7	37.8	132
5	PRE	385	40.9	22.4	26.9	115
6	PRE	385	51.8	25.1	31.8	139
7	PRE	387	74.3	41.7	46	245
7	2HR	398	94.6	63	46.3	205
7	4HR	409	132	85.4	61.4	310
7	6HR	394	142	83.8	74.1	351
7	8HR	398	136	79.3	59.9	296
7	12HR	384	111	62.1	54.2	286
8	PRE	402	63.1	31.7	38.4	211
9	PRE	417	101	53.4	59	283
10	PRE	390	76.4	40.8	65	363
11	PRE					
12	PRE					
13	PRE					
14	PRE					
14	2HR					
14	4HR					
14	6HR					
14	8HR					
14	12HR					

Table 13f-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 08

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE					
16	PRE					
17	PRE					
18	PRE					
19	PRE					
20	PRE					
21	PRE					
21	2HR					
21	4HR					
21	6HR					
21	8HR					
21	12HR					
22	PRE					
25	PRE					
29	PRE					
32	PRE					
33	PRE					
36	PRE					
39	PRE					
42	PRE					
42	.5HR					
42	1HR					
42	2HR					
42	3HR					
42	4HR					
42	6HR					
42	8HR					
42	10HR					
42	12HR					
43	AM					
44	AM					
45	AM					
48	AM					
51	AM					
54	AM					
57	AM					
72	AM					
180	AM					

Table 13g-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 09

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	395				
1	.5HR	374				
1	1HR	375				
1	2HR	359	12.6	11.2		
1	3HR		70.9	61.8		
1	4HR	386	152	132		20.4
1	6HR	401	122	102		24.3
1	8HR	391	103	81.4		27.6
1	10HR	381	65	47		26.6
1	12HR	391	53.8	37.4		23
2	PRE	368	21	15.2		24
3	PRE	393	20.6	13.4		33.2
4	PRE	416	24.2	16.5		44.1
4	2HR	384	42.8	29.5		51.7
4	4HR	403	109	73.3	23.1	78.5
4	6HR	391	95.8	63.6	15.2	64.3
4	8HR	385	60.5	42.5	16.6	55
4	12HR	409	38.6	24.1	15.7	44.1
5	PRE	384	27	17.5	17.8	85.8
6	PRE	397	36.7	20.5	15.2	62.6
7	PRE	372	40.9	23.4	21.7	111
7	2HR	358	36.1	21.4	18.7	79.8
7	4HR	389	122	86.7	41.5	194
7	6HR	407	122	87	33.2	176
7	8HR	396	94.1	60.8	28.5	125
7	12HR	406	64.8	43.5	35.3	164
8	PRE	399	44.6	28	29.1	158
9	PRE	428	57.4	35.1	29.7	138
10	PRE	411	51.6	29	25.5	153
11	PRE	391	60.3	36.9	45.3	240
12	PRE	413	65.4	43.4	36.8	228
13	PRE	423	58.9	33.1	29.1	180
14	PRE	398	53.1	30	27.3	174
14	2HR	412	74.7	49	27	176
14	4HR	406	166	124	56.9	382
14	6HR	393	162	119	51.9	337
14	8HR	411	166	130	73.2	423
14	12HR	417	132	92.1	63.7	400

Table 13g-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 09

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	374	59.6	35.5	34.4	252
16	PRE	421	62.3	37.8	42.1	289
17	PRE	368	68.6	41.2	31.7	264
18	PRE	427	81.9	54.1	39.1	300
19	PRE	427	164	120	53.3	386
20	PRE	440	234	166	47.7	312
21	PRE	433	221	155	66.4	384
21	2HR	416	111	73.3	59.8	386
21	4HR	438	91.2	55.6	54.5	393
21	6HR	438	42.5	25.4	45.6	313
21	8HR	410	58.1	36.8	42.4	364
21	12HR	409	86.4	60.2	42.4	282
22	PRE					
25	PRE	432	42	20.6	30.2	227
29	PRE	419	58.4	32.8	44.8	263
32	PRE	415	56.5	34.3	35	251
33	PRE	470	54.9	29.4	19.9	147
36	PRE	387	46	29.9	19	126
39	PRE	391	104	68.9	30.8	227
42	PRE	417	81	50.9	36.8	255
42	.5HR	413	88	52.6	19.3	139
42	1HR	413	120	73.2	37.1	256
42	2HR	419	90.9	49.6	35	181
42	3HR	424	72.9	43.2	32	207
42	4HR	420	70.8	40.4	32.3	217
42	6HR	418	54.9	29.4	30.5	222
42	8HR	413	37.3	21.1	28.2	205
42	10HR					
42	12HR	404	25.8	15		113
43	AM	454	17.8			73.5
44	AM	384	22	12.2		73.5
45	AM	433	20.1	10.7		42.2
48	AM	367	13.2	56.5		22
51	AM	388		44.8		
54	AM					
57	AM					
72	AM					
180	AM					

Table 13h-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 10

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	398				
1	.5HR	392				
1	1HR	400				
1	2HR	402	19.6	28.8		
1	3HR	409	63.2	72.8		29.3
1	4HR	399	103	88.5	15.1	31
1	6HR	395	86.9	66	16.5	33.7
1	8HR	396	75.5	61.7	16.7	33.7
1	10HR	406	58.1	56.2		32.2
1	12HR	400	43.5	47.6		23
2	PRE	377	23.3	21.4		20.4
3	PRE	404	20	12.4		33.5
4	PRE	404	28.4	23.3	18.4	45.9
4	2HR	413	32.9	30	19.2	51.8
4	4HR	412	70.9	56.9	19.4	70.1
4	6HR	405	63.2	46.7	20.2	66.8
4	8HR	412	49.2	37.1	24.8	73.1
4	12HR	414	34.1	23	24.2	68.7
5	PRE	412	24.3	15.4	21.7	71.4
6	PRE	409	20.5	16.5	19.2	71
7	PRE	410	19.8	14.2		51
7	2HR	419	43.5	37.5		60
7	4HR	405	63.3	54.6	19	79
7	6HR	399	65.4	63.9	18.8	70.3
7	8HR	418	51.7	43.9	16.5	67.4
7	12HR	406	31.4	25.1		54.3
8	PRE	414	29.1	21.4	15.3	61.1
9	PRE	414	81.7	50.4	28.8	104
10	PRE	438	62	45.4	22.1	103
11	PRE	420	45.1	32.1	33.5	137
12	PRE	418	58.1	34.7	22.1	90.6
13	PRE	406	47.6	28	20.3	81.9
14	PRE	402	56.2	45.2	18	73.7
14	2HR	406	167	140	20.9	96.9
14	4HR	442	334	359	36.8	132
14	6HR	439	259	192	40.8	150
14	8HR	450	283	196	48.3	156
14	12HR	420	178	109	40.2	152

Table 13h-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 10

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	440	98.6	57.7	45.3	207
16	PRE	420	83.6	45.4	41.4	202
17	PRE	415	65.9	37.4	33.5	200
18	PRE	403	224	200	43.7	245
19	PRE	433	359	333	47.4	209
20	PRE	451	278	192	55.5	213
21	PRE	429	254	172	61.1	255
21	2HR	446	173	109	44.7	200
21	4HR	416	95.1	51.1	38.5	212
21	6HR	405	98.4	62.7	46.4	232
21	8HR	432	87.9	53.5	36	216
21	12HR	414	136	82.1	43.5	215
22	PRE					
25	PRE	377	118	64.5	57.4	287
29	PRE	414	94.6	47.4	50.3	301
32	PRE	413	67.8	35.6	26.1	178
33	PRE	373	83.7	44	31.7	236
36	PRE	392	54.5	37.8	19.8	151
39	PRE	379	165	124	54.9	403
42	PRE	445	435	468	44.1	481
42	.5HR	436	318	261	48.7	324
42	1HR	411	303	234	68.2	431
42	2HR	410	204	150	47.4	326
42	3HR	419	259	184	55.9	340
42	4HR	418	203	128	56.3	314
42	6HR	430	127	80.5	60.3	420
42	8HR	415	58.9	33.3	31.5	255
42	10HR					
42	12HR	406	43.2	37		198
43	AM	411	36.1	30.9		168
44	AM	404	24.7	23.4		106
45	AM					
48	AM					
51	AM					
54	AM					
57	AM					
72	AM					
180	AM					

Table 13I-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 11

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	412				
1	.5HR	421				
1	1HR	414	17.9	16.9		
1	2HR	409	34.8	27.4		
1	3HR	455	31.2	23		
1	4HR	474	80	50.9	24.2	45.7
1	6HR	414	42.2	24.8		20.8
1	8HR	414	41	22.9	17.2	31
1	10HR	415	39.9	23	16.9	31.3
1	12HR	416	28.4	16.5	17.9	35.7
2	PRE	423	17.1		16.2	31.5
3	PRE	444	83.1	47.5	44	100
4	PRE	435	44.8	22.1	40.9	96.3
4	2HR	425	63.4	44.6	41.4	95
4	4HR	437	134	96.9	59.7	164
4	6HR	416	103	69.9	53.8	137
4	8HR	448	99.4	65.6	51.9	137
4	12HR	439	79.3	48.7	45.1	125
5	PRE	439	48.5	29.5	41.6	103
6	PRE	444	57.6	34.4	46.8	139
7	PRE	421	32.5	21.6	29.8	84.8
7	2HR	434	55.4	42.4	30.6	101
7	4HR	424	109	79.1	47.5	142
7	6HR	429	85.8	56.7	36.2	103
7	8HR	437	75	49.1	33.6	94.8
7	12HR	410	59.3	37.5	32.9	93.4
8	PRE	424	33.3	20	32	96.9
9	PRE	423	43.5	25.8	35.7	126
10	PRE	430	34.1	21.1	25.6	86.6
11	PRE	427	41.7	26.2	26.6	97.4
12	PRE	412	41.3	23.7	27.7	102
13	PRE	407	58.5	36.4	42.1	167
14	PRE	438	43.9	31.3	32	135
14	2HR	409	67.2	52.7	25.9	102
14	4HR	447	216	205	41.1	157
14	6HR	436	302	264	47.5	167
14	8HR	439	324	269	41.8	133
14	12HR	452	187	159	50.3	155



Table 13I-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 11

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	431	73.9	41.7	44.4	193
16	PRE	458	60.5	30.9	33.6	137
17	PRE	451	65.6	34.6	27.7	130
18	PRE	454	67.1	40.4	31.3	118
19	PRE	441	86.2	58.9	27	98.7
20	PRE	450	127	87.4	39.3	195
21	PRE	483	96.8	65.6	32.7	131
21	2HR	438	81.4	50.8	39.3	176
21	4HR	440	56.1	29.9	27.5	120
21	6HR	474	54.1	29.1	32.9	125
21	8HR	441	46.4	25.8	28.9	150
21	12HR	438	63.4	37.8	35.7	154
22	PRE					
25	PRE					
29	PRE	452	72.3	42	58.1	201
32	PRE	473	54.5	30.1	39.5	201
33	PRE	434	49.4	27.3	39.7	166
36	PRE	418	60.3	39.6	48.2	203
39	PRE	451	142	115	66.1	319
42	PRE	491	176	127	65.6	307
42	.5HR	476	205	147	74	390
42	1HR	478	135	93.6	49.8	233
42	2HR	471	111	67.8	51.9	230
42	3HR	425	155	98.2	77.6	367
42	4HR	450	92.9	55.2	46.8	251
42	6HR	434	54.2	31.5	45.4	225
42	8HR	427	43.6	24.3	35.7	204
42	10HR	463	38.5	22.3	24.4	162
42	12HR					
43	AM					
44	AM					
45	AM					
48	AM					
51	AM					
54	AM					
57	AM					
72	AM					
180	AM					

Table 13j-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 14

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	403				
1	.5HR	406				
1	1HR	399				
1	2HR	421	11.2			
1	3HR	416	24.8	13.7		
1	4HR	389	44	19.5		17.1
1	6HR	385	49.2	22.3		15.6
1	8HR	426	50.4	20.7		19.1
1	10HR	419	50.7	19.7		22.6
1	12HR	426	34.5	12.7		22.3
2	PRE	420	18.9			18.8
3	PRE	403	16.9			19.4
4	PRE	408	28.4			33.3
4	2HR	412	39.8	19.2		38.6
4	4HR	410	48.7	23.7	15.8	59.8
4	6HR	403	68	29.1	15.8	59.5
4	8HR	407	44.8	15		33.6
4	12HR	398	38.6	13.2		45.8
5	PRE	404	28.7	10.3		29.6
6	PRE	419	47.1	17.3		83.3
7	PRE	412	52.5	17.6		53.4
7	2HR	413	40.9	23.9		59.2
7	4HR	416	66	27		70.5
7	6HR	412	73.3	29.6	18.2	84.7
7	8HR	420	53.3	19.9		63
7	12HR	420	45.6	13.6		51.1
8	PRE	413	39.2	12.9		55.1
9	PRE	413	50.3	16.9	15.6	72
10	PRE	424	96.8	33.6	26.5	116
11	PRE	428	99.7	33.3	20.5	97.8
12	PRE	421	99.5	30	28.6	155
13	PRE	418	71.6	23.9	25.2	196
14	PRE	413	73.3	22.8	28.4	195
14	2HR	419	99.8	40.4	34.4	298
14	4HR	413	168	82.6	50	320
14	6HR	413	176	87.9	44	317
14	8HR	405	182	84	55.5	374
14	12HR	417	104	42	39.6	299

Table 13j-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 14

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	422	91.6	29.1	35.2	320
16	PRE	421	90	27.6	31.2	303
17	PRE	421	60.4	18.4	20	199
18	PRE	415	156	69.5	37.8	336
19	PRE	413	154	65.1	31.2	233
20	PRE	420	140	62.2	29.9	244
21	PRE	414	99.8	40.9	23.1	176
21	2HR	421	86.2	29.1	22.1	161
21	4HR	416	74.7	22.6	29.4	292
21	6HR	444	126	38.3	32.8	339
21	8HR	450	272	91.3	56.3	460
21	12HR	430	215	72.6	38	311
22	PRE					
25	PRE	448	206	61.6	48.5	401
29	PRE	438	223	70.6	54.5	405
32	PRE					
33	PRE					
36	PRE					
39	PRE					
42	PRE					
42	.5HR					
42	1HR					
42	2HR					
42	3HR					
42	4HR					
42	6HR					
42	8HR					
42	10HR					
42	12HR					
43	AM					
44	AM					
45	AM					
48	AM					
51	AM					
54	AM					
57	AM					
72	AM					
180	AM					

Table 13k-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 15

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	401				
1	.5HR	388				
1	1HR	349				
1	2HR	395	23.9	19.6		
1	3HR	374	28.6	19.9		
1	4HR	395	44	26.9		15.7
1	6HR	397	43.7	23.9		
1	8HR	392	38.6	20.7		
1	10HR	388	31.9	14.1		
1	12HR	388	22.3			
2	PRE	399	13			
3	PRE	405	39.1	18.8		23.9
4	PRE	381	33.7	14		50.3
4	2HR	416	61.1	37.1		58.1
4	4HR	396	70.6	39.7	18	88.6
4	6HR	383	70.2	36.5	22.3	108
4	8HR	401	59.7	28.3	20.9	89.7
4	12HR	381	47.3	21		68.8
5	PRE	388	33.2	12.2		41
6	PRE	404	35.1	13	16.9	89
7	PRE	398	34.6	12.2	16.3	97.5
7	2HR	383	58.5	33.8	15.3	87.9
7	4HR	395	100	57.7	20.9	149
7	6HR	365	98.2	54.4	20	112
7	8HR	394	72.6	36.9		53.8
7	12HR	371	68.8	27.5		49.2
8	PRE	397	34.8	14.4		83.6
9	PRE	396	30.4	13.3		55.1
10	PRE	401	47.1	22.1	20	120
11	PRE	404	50.4	23.7	16.7	102
12	PRE	388	49.7	22.8	20.2	135
13	PRE	401	35.1	17.7	16.9	110
14	PRE	396	53.1	24.8	19.8	154
14	2HR	398	94.8	61.6	27.5	186
14	4HR	430	107	65.2	36.2	221
14	6HR	410	138	75.5	22.3	137
14	8HR	409	121	64.9	30.8	180
14	12HR	398	91.5	41.1	24.4	169

Table 13k-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 15

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	409	51.6	23.1	21.3	167
16	PRE	397	53.8	29.5	21.3	188
17	PRE	392	38.2	17		137
18	PRE	401	85.4	49.4	20.7	180
19	PRE	435	142	94.3	31.8	250
20	PRE	416	145	92.5	22.3	173
21	PRE	409	125	76.3	31.2	251
21	2HR	403	89.6	50.1	20.9	178
21	4HR	394	49.7	24.8	28.7	221
21	6HR	423	40.1	18.5	22.9	161
21	8HR	418	86.2	43.9	42	319
21	12HR	402	94.5	48.7	42	346
22	PRE					
25	PRE	407	77.9	34.5	33.1	332
29	PRE	404	75.4	36.5	36.4	342
32	PRE	406	76.1	35.8		182
33	PRE	393	90.5	44.8	20.2	242
36	PRE	410	100	54.1	31.2	375
39	PRE	392	108	56.8	18.8	199
42	PRE	414	151	86	52.3	514
42	.5HR	389	138	73.5	39.1	372
42	1HR	408	123	64.4	19.6	163
42	2HR	404	124	66.2	26.7	270
42	3HR	402	114	58.1	29.1	284
42	4HR	420	128	66.9	38.3	326
42	6HR	415	89.1	42.7	34.3	406
42	8HR	401	65.8	32	20.9	270
42	10HR	395	46.2	22.1	17.3	272
42	12HR	389	33	12.8		188
43	AM	399	26.2			106
44	AM	347	31.5	12.4		72.2
45	AM	383	20.2			26.9
48	AM	432	22.1			
51	AM	397				
54	AM					
57	AM					
72	AM					
180	AM					

Table 13L-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 16

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	380				
1	.5HR	396				
1	1HR	393				
1	2HR	390	18.1	12.9		
1	3HR	400	38.7	25.9		
1	4HR	400	40.3	24.4		
1	6HR	394	21.7	11.1		
1	8HR	374	19.8			
1	10HR	400	20.1	10.2		16.6
1	12HR	400	20.6			19.5
2	PRE	392	11			18.5
3	PRE	382	18.9			49.1
4	PRE	399	28.5	13.6		78.1
4	2HR	395	51.2	30.4		85.1
4	4HR	396	94.1	54.3	18.7	132
4	6HR	399	68.6	37.2	18.2	99.5
4	8HR	401	55.7	28.6		77.5
4	12HR	401	46.9	23.4	22.7	128
5	PRE	403	35.2	16.6	17.6	123
6	PRE	404	42.7	20.7	29.3	200
7	PRE	405	53.1	24.1	36.7	267
7	2HR	404	83.3	50.3	35.6	238
7	4HR	401	153	87.3	24.7	157
7	6HR	400	189	105	20.7	146
7	8HR	399	128	66.8	34.7	214
7	12HR	407	87.3	43.7	35.6	254
8	PRE	406	49.1	23.4	27.6	226
9	PRE	405	57.5	26.1	32.7	256
10	PRE	400	55.4	24.9	41.6	335
11	PRE	408	58.5	27.9	31.6	292
12	PRE	397	57.1	28.7	31.6	290
13	PRE	411	67.5	29.4	33.3	317
14	PRE	402	64.8	27.9	32.5	334
14	2HR	416	73.8	38.7	36.5	354
14	4HR	403	107	57.6	52.2	462
14	6HR	404	132	68.9	55.9	473
14	8HR	403	90.9	46.8	48.7	430
14	12HR	400	101	44.2	48.7	430

Table 13L-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 16

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	403	81.8	35.1	49.6	561
16	PRE	411	94	40.9	51.9	588
17	PRE	404	97.7	38.6	43.3	521
18	PRE	391	110	58.3	43.9	587
19	PRE	421	219	125	45	548
20	PRE	414	215	120	45.6	532
21	PRE	410	152	80.8	68.7	715
21	2HR	411	151	69.6	51.6	492
21	4HR	400	91.5	39.2	37.6	552
21	6HR	420	85.9	36.1	44.2	569
21	8HR	426	69.8	30.7	34.7	393
21	12HR	434	138	66.9	41.6	510
22	PRE					
25	PRE	424	152	68.4	47.9	497
29	PRE	427	242	115	73	594
32	PRE	438	87.7	39.7	28.2	335
33	PRE	420	108	47.8	31.9	375
36	PRE	407	90.5	41.2	32.2	344
39	PRE	403	120	63.3	32.2	381
42	PRE	433	208	114	47.9	524
42	.5HR	408	242	137	43.3	480
42	1HR	416	183	96.5	28.2	383
42	2HR	414	143	71.4	33	363
42	3HR	410	178	86.3	42.7	484
42	4HR	415	119	57.8	33.3	368
42	6HR	419	114	49.6	28.5	377
42	8HR	422	114	46.6	41	563
42	10HR					
42	12HR					
43	AM					
44	AM					
45	AM					
48	AM	399	21.1			38.9
51	AM	416				
54	AM					
57	AM					
72	AM					
180	AM					

Table 13m-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 18

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	403				
1	.5HR	394				
1	1HR	400				
1	2HR	409	24.1	20.5	28.4	
1	3HR	403	82.5	75.1	16.5	22.6
1	4HR	403	147	128	15.5	22.6
1	6HR	402	105	83.2	16.3	23.3
1	8HR	403	85.9	58.9	18.5	31.3
1	10HR	409	76.2	49.3	15.5	32.7
1	12HR	402	61.2	38.3	16.3	28.9
2	PRE	409	60.6	26.6	20.4	95.7
3	PRE	411	29.3	15		24.8
4	PRE	416	67.1	31.1	23.4	124
4	2HR	412	74.3	42.3	19.5	116
4	4HR	413	116	74.2	25.4	138
4	6HR	441	156	94.3	23.2	126
4	8HR	411	114	64.4	19.5	91.6
4	12HR	415	95.9	48	18.9	96.8
5	PRE	422	60.5	27.8	25.6	135
6	PRE	415	66	32.3	31.2	190
7	PRE	421	114	56.4	27.2	182
7	2HR	410	82.4	45.2	26	153
7	4HR	438	224	158	33.4	213
7	6HR	435	226	153	28.2	191
7	8HR	422	87.4	41.9	24.8	207
7	12HR	421	141	78.4	26	153
8	PRE	418	87.9	41	28.6	204
9	PRE	451	82.2	35.8	27	235
10	PRE	422	91.2	41.2	32.8	235
11	PRE	416	85.4	37.1	39	239
12	PRE	419	103	43.4	38.2	299
13	PRE	440	85	37.1	26.4	265
14	PRE	430	87.9	36.8	28.4	267
14	2HR	425	171	102	35	222
14	4HR	428	166	107	37.6	293
14	6HR	425	149	95.6	30.2	306
14	8HR	420	118	67.1	26.4	267
14	12HR	428	125	62.6	33.8	218



Table 13m-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 18

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	452	86.5	35.4	28.4	216
16	PRE	432	81.3	33.9	28.2	219
17	PRE	426	90.8	36.8	27.8	202
18	PRE	414	113	57.9	31.8	254
19	PRE	437	147	82.6	23.4	245
20	PRE	446	186	102	31.4	227
21	PRE	428	166	83.1	30.8	253
21	2HR	428	116	52.7	23.2	211
21	4HR	431	93	37.1	27.6	197
21	6HR	450	56.7	24.7	17.7	212
21	8HR	426	70.1	32.7	19.7	182
21	12HR	453	157	87.4	29.8	173
22	PRE					
25	PRE					
29	PRE					
32	PRE	475	213	112	39.2	384
33	PRE	462	215	127	37.8	389
36	PRE	456	201	117	37.8	377
39	PRE	434	209	159	38.4	438
42	PRE	464	219	157	33.8	394
42	.5HR	454	293	204	33.6	393
42	1HR	420	311	198	43.3	402
42	2HR	415	260	166	37.8	352
42	3HR	426	237	133	45.3	335
42	4HR	428	247	128	32.8	353
42	6HR	423	165	80	31.8	294
42	8HR	445				
42	10HR	440	110	47.3	18.1	273
42	12HR		54.8	20.7	17.7	291
43	AM	424	58.9	21.7		215
44	AM	419	42.3	20.2		141
45	AM	415	42.7	17.3		73.2
48	AM	416	27.7	14		43.3
51	AM					
54	AM					
57	AM					
72	AM					
180	AM					

Table 13n-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 19

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	395				
1	.5HR	377				
1	1HR	366	26.6	23.2		
1	2HR	389	40.7	34.7	18.4	
1	3HR	404	48	34.5	15.8	
1	4HR	418	40.9	27.8		
1	6HR	402	60.4	37.4		17.2
1	8HR	402	37.8	20.8		15.3
1	10HR	405	45.2	24.7		15.3
1	12HR	404	34.3	19.2		20.1
2	PRE	402	26.6	13.4	22	16.4
3	PRE	422	44.7	26.9		33.6
4	PRE	410	50.4	29	15.5	40.2
4	2HR	404	65	43.1	23.1	60
4	4HR	409	151	115	23.6	62.2
4	6HR	410	145	107		65.6
4	8HR	418	110	77.9	23.1	77
4	12HR	404	66	44.2		58.5
5	PRE	404	50.5	31.4		66.9
6	PRE	404	52.5	31.6	15.5	88.6
7	PRE	403	53.6	27.8	15.8	99.5
7	2HR		104	78.8		116
7	4HR	403	155	121	17.2	115
7	6HR	413	130	99.7		107
7	8HR	421	87.8	67.9		49.5
7	12HR	408	81.9	53		68
8	PRE	403	61	46.6	15.3	120
9	PRE	409	44.5	32.1	15.5	119
10	PRE	406	64	45.2	27.7	157
11	PRE	407	57.5	37.7	20.5	147
12	PRE	408	60.9	44.1	25.3	187
13	PRE	393	57.8	37.7	22.2	176
14	PRE	416	59.9	35.7	23.9	222
14	2HR		98.1	68.9	26	242
14	4HR		210	131	17.7	223
14	6HR		197	120	18.9	151
14	8HR		164	103	24.8	179
14	12HR		121	65.7		110

Table 13n-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 19

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	411	86.7	45.6		136
16	PRE	408	110	59.5		127
17	PRE	396	89.9	66.8	20.1	183
18	PRE	404	51.1	41.9		138
19	PRE	407	123	88.8		109
20	PRE	405	76.3	73.7	26.2	248
21	PRE	405	77.9	59.4	34.3	285
21	2HR	405	43.4	32.9	17	166
21	4HR	410	33	22.6	19.8	186
21	6HR	408	29.6	17.8		188
21	8HR	411	37.3	24.9	17.4	231
21	12HR	442	40.1	27.1	18.9	217
22	PRE		52	33.7	21.7	278
25	PRE	420	49.6	32.4	21.2	231
29	PRE	401	55.2	35.5	29.3	309
32	PRE	440	44.9	30		179
33	PRE	409	45.9	29		200
36	PRE	398	56.4	38.1	21.7	253
39	PRE	405	74.2	55	19.3	259
42	PRE	416	105	77	28.1	298
42	.5HR	406	106	70.3	23.9	278
42	1HR	403	149	87.6	33.1	293
42	2HR	410	101	63.5	33.8	271
42	3HR	403	82.2	51.4	28.4	286
42	4HR	410	80.6	46.3	23.1	268
42	6HR	406	61.5	35.8	19.1	247
42	8HR	398	40.8	22.1	16.7	214
42	10HR	393	32	17.6	18.6	236
42	12HR	406	27.8	11.8		72.5
43	AM	415	19.5	10.5		97.6
44	AM	367	15.8	10.2		50
45	AM	401	13.1	11		28
48	AM	403				
51	AM					
54	AM					
57	AM					
72	AM					
180	AM					

Table 13o-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 20

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
1	PRE	422				
1	.5HR	392				
1	1HR	415				
1	2HR	404				
1	3HR	402	14.8	13.8		18.2
1	4HR	402	24.2	18.1		24.6
1	6HR	398	19.5	12.9		29.4
1	8HR	398	12.7			29
1	10HR	392				30.3
1	12HR	402				31.7
2	PRE	4368			47.5	48.7
3	PRE	383				48
4	PRE	397	15	11.5	23.6	105
4	2HR	422	22.3	20.2	24	92.7
4	4HR	404				106
4	6HR	403				26
4	8HR	413	36	26	32.3	139
4	12HR	416	30.2	23.4	26	108
5	PRE	378	17.6	12.1	23.1	113
6	PRE	411	19.2	15.8	28.7	128
7	PRE	407	20.1	15.4	22.1	147
7	2HR	411	30	23.9	29.1	159
7	4HR	413	82.2	68.7	181	201
7	6HR	408	39.5	32.9	28.5	155
7	8HR	400	38.2	28.7	31.4	159
7	12HR	405	30	17.7	25.8	131
8	PRE	411	24.2	20.5	28.7	169
9	PRE	407	23.2	20	29.4	169
10	PRE	413	28.2	17.9	26	184
11	PRE	409	23.1	17.9	31.8	184
12	PRE	425	20.4	14.7	29.4	183
13	PRE	415	29.3	23	34.1	190
14	PRE	411	29.7	22	26.9	183
14	2HR	405	28.2	20.5	22.5	178
14	4HR	410	47.1	36.9	40.7	176
14	6HR	410	40.5	29	37	205
14	8HR	426	55.2	42.1	36	209
14	12HR	424	50	30.8	26.5	171

Table 13o-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 20

<u>Day</u>	<u>Time</u>	<u>QTc</u>	<u>Halo +</u>	<u>Halo -</u>	<u>Metab +</u>	<u>Metab -</u>
15	PRE	402				20
16	PRE	409	32.9	23.2	21.1	162
17	PRE	410	36.5	20.4	21.9	134
18	PRE	411	41.6	33.8	27.9	176
19	PRE	417	83.8	59.7	33.3	192
20	PRE	417	51.7	34.8	26.5	163
21	PRE	432	56	37.3	25.6	170
21	2HR	416	45.6	30.4	31	154
21	4HR	424	19.2	13.1	20.7	153
21	6HR	415	40.8	24.6	18.6	115
21	8HR	448	78.4	57.1	39.1	201
21	12HR	426	41.1	26	49	329
22	PRE		35.9	22.5	42	264
25	PRE	427	36.9	18.1	53.1	420
29	PRE	421	22.4	14.4	43	385
32	PRE	438	33.8	17	28.5	304
33	PRE	437	27	17.2	33	330
36	PRE	425	40.8	24.8	40.9	389
39	PRE	428	35.7	26.4	38.7	346
42	PRE	442	71	57.5	49.3	424
42	.5HR	442	66.1	50.2	45.9	416
42	1HR	435	80.3	53.4	41.1	386
42	2HR	420	63.6	42.8	45.9	429
42	3HR	416	57.3	37.3	42.7	383
42	4HR	425	49.5	37.7	41.6	304
42	6HR	414	34.3	22.3	33.2	309
42	8HR	411	21.7	14.2	31.4	283
42	10HR	411	17.4		24.2	309
42	12HR	412				159
43	AM	414				117
44	AM	407				
45	AM	382			34.8	51.9
48	AM	409	18.9		31.9	48.8
51	AM		12.9		29.4	64
54	AM					
57	AM					
72	AM					
180	AM					

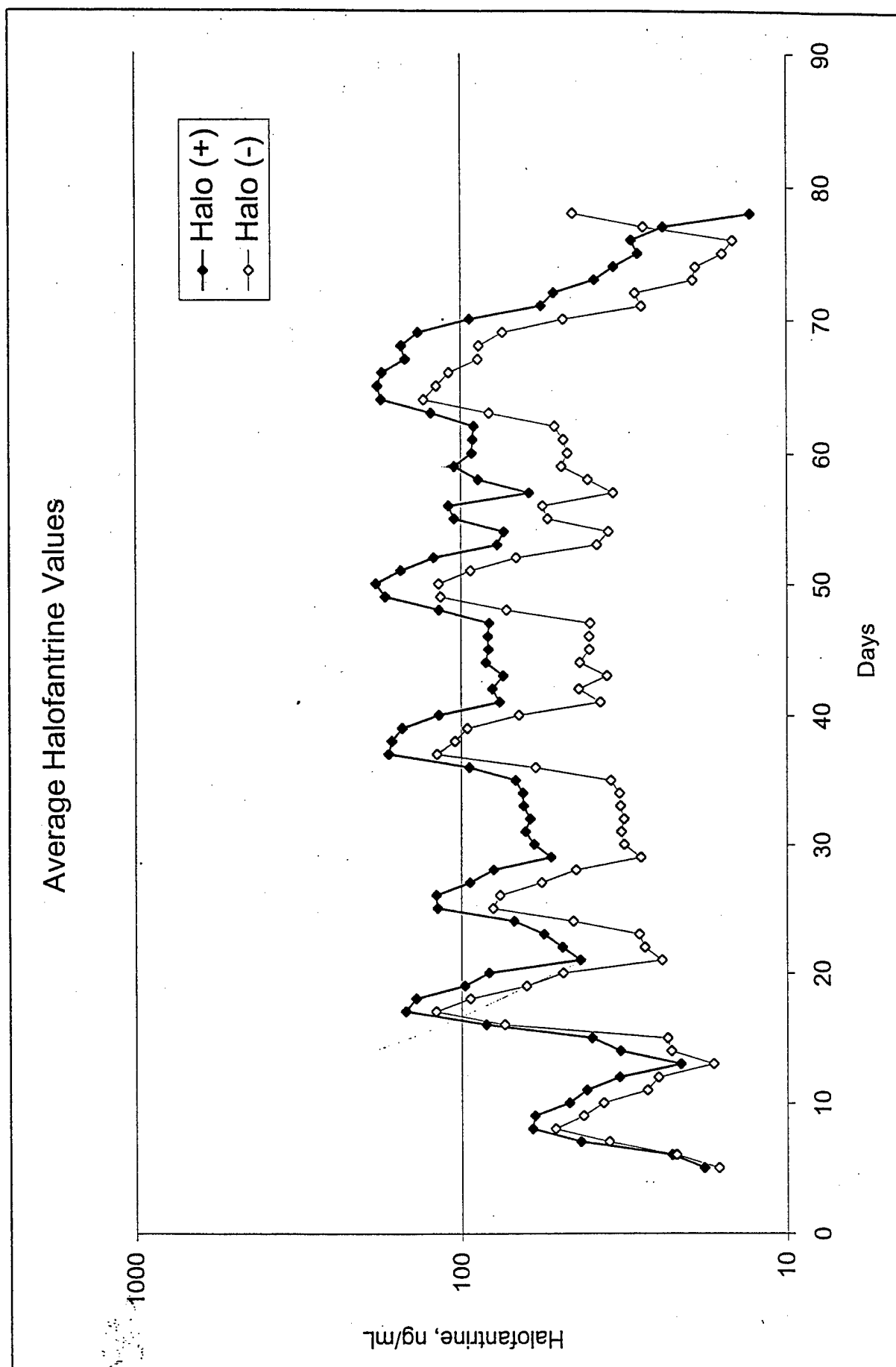


Figure 55a: Halofantrine and Metabolite Concentrations for Subject 01

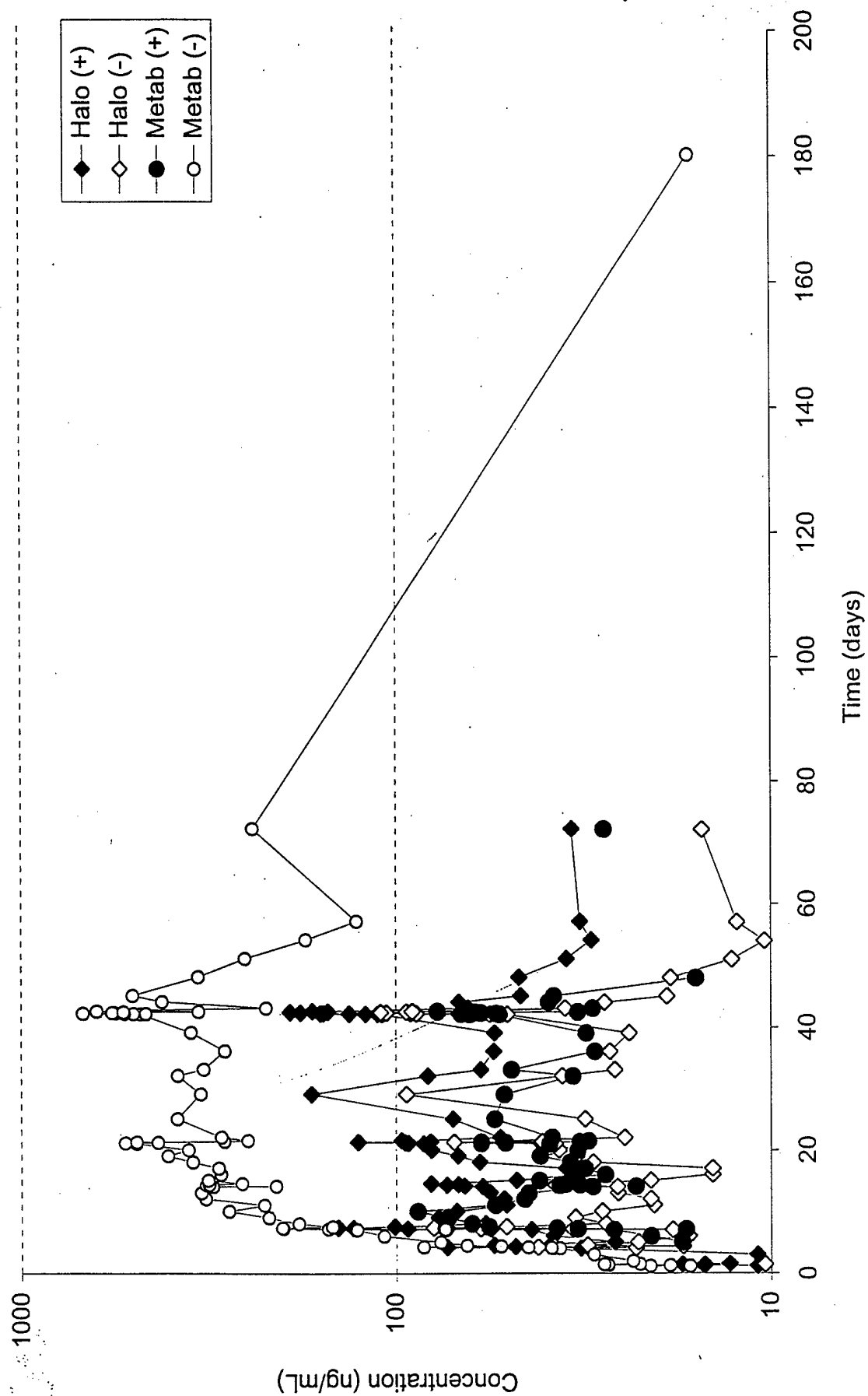


Figure 55b: Halofantrine and Metabolite Concentrations for Subject 02

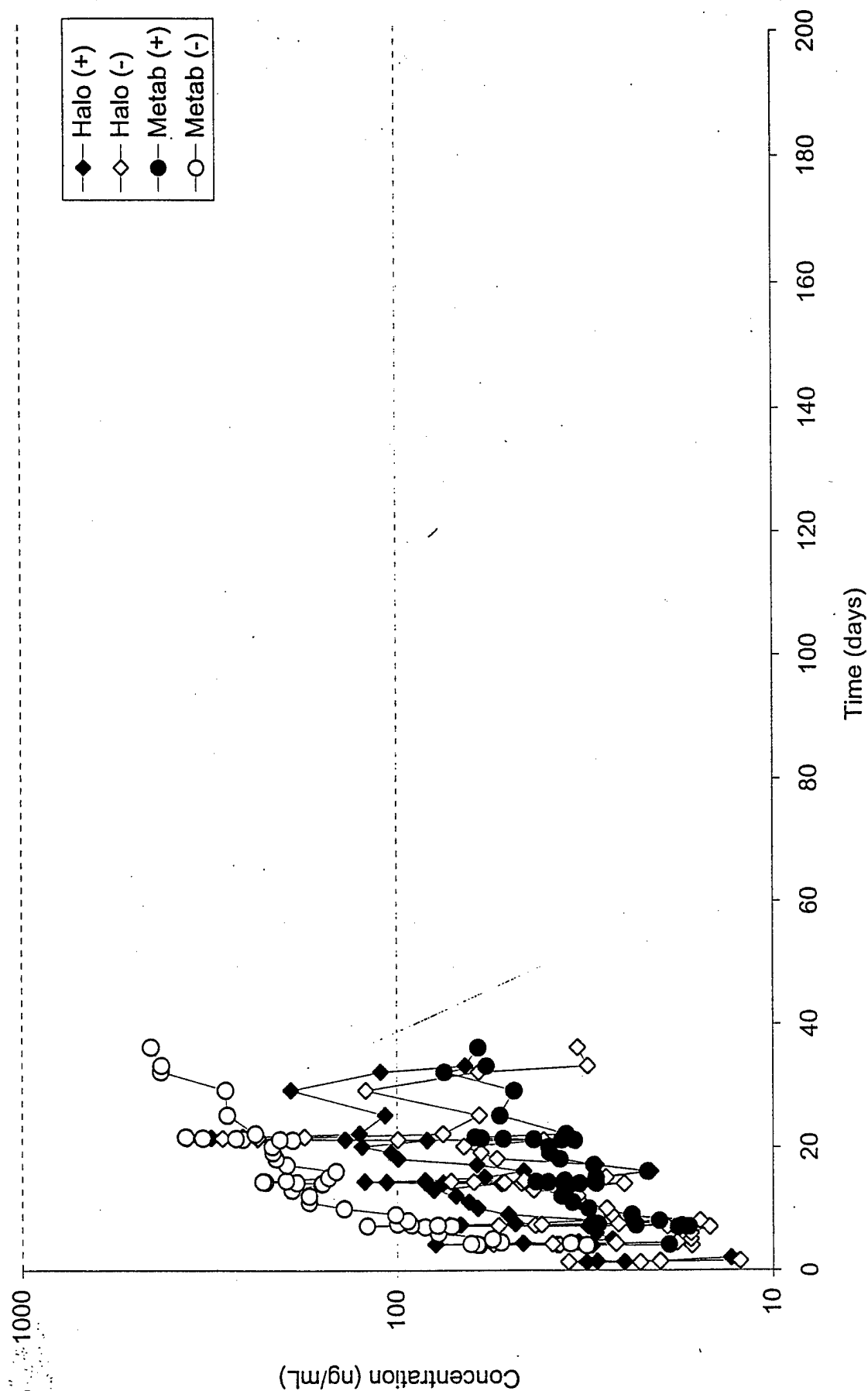




Figure 55c: Halofantrine and Metabolite Concentrations for Subject 04

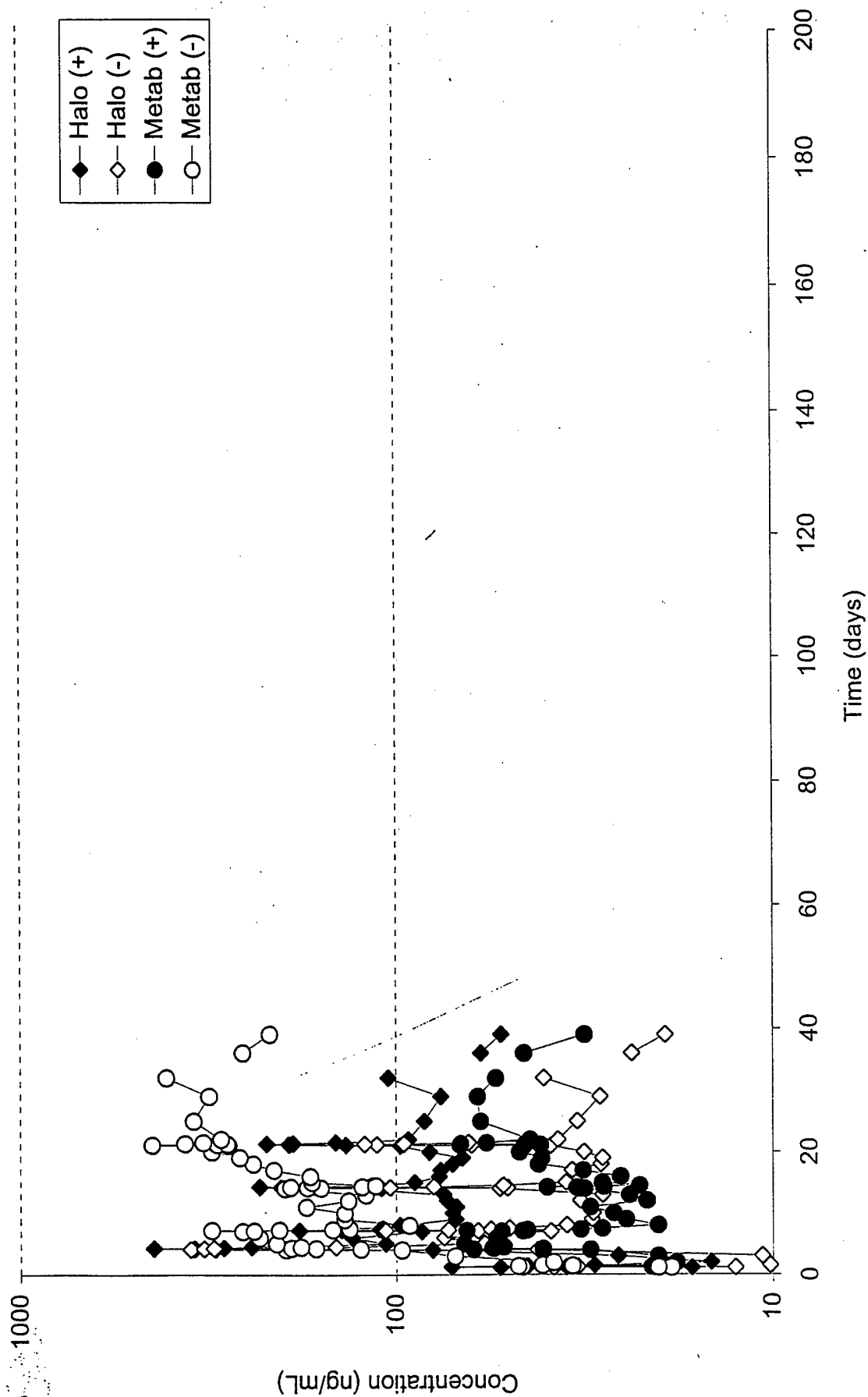


Figure 55d: Halofantrine and Metabolite Concentrations for Subject 05

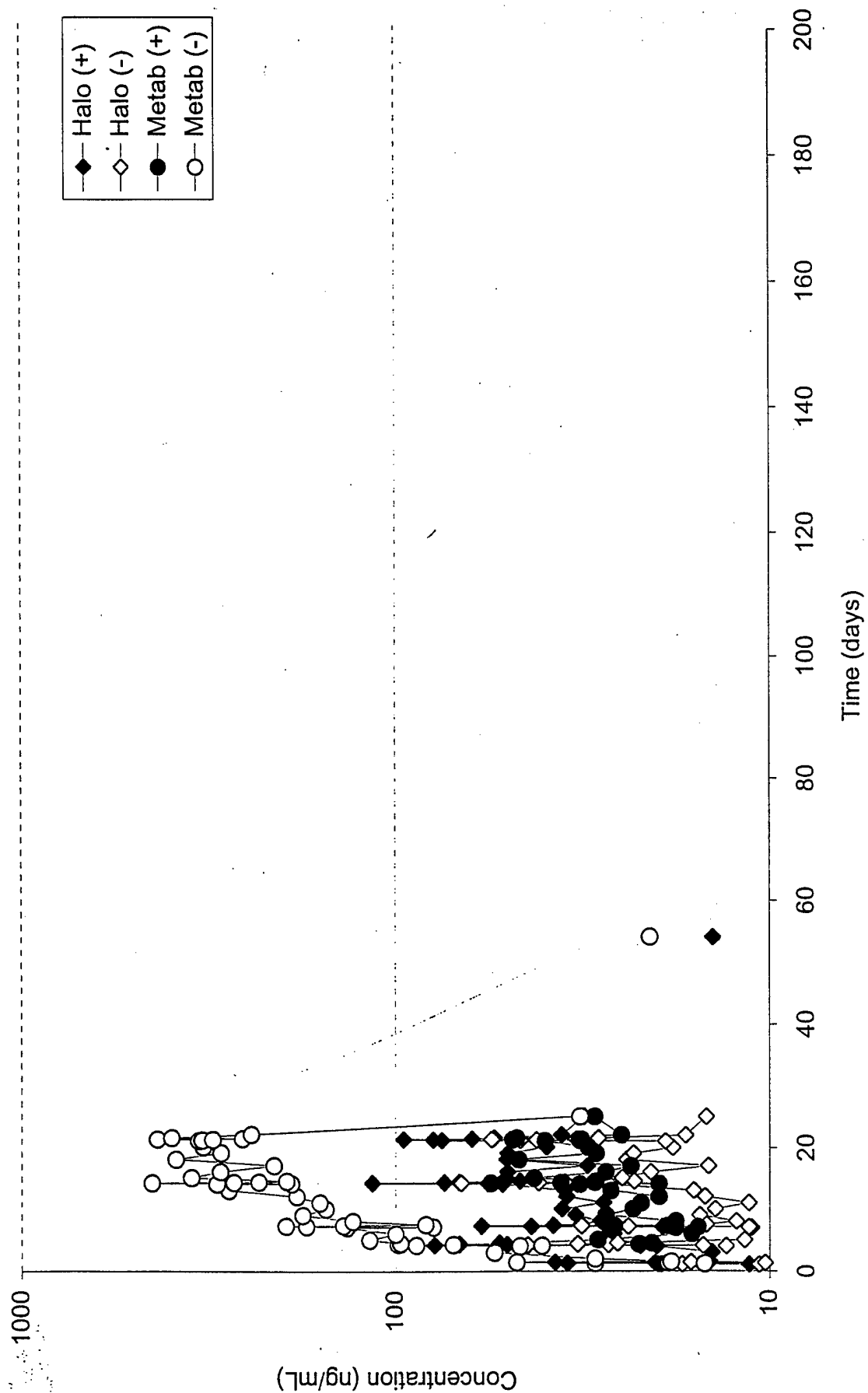


Figure 55e: Halofantrine and Metabolite Concentrations for Subject 07

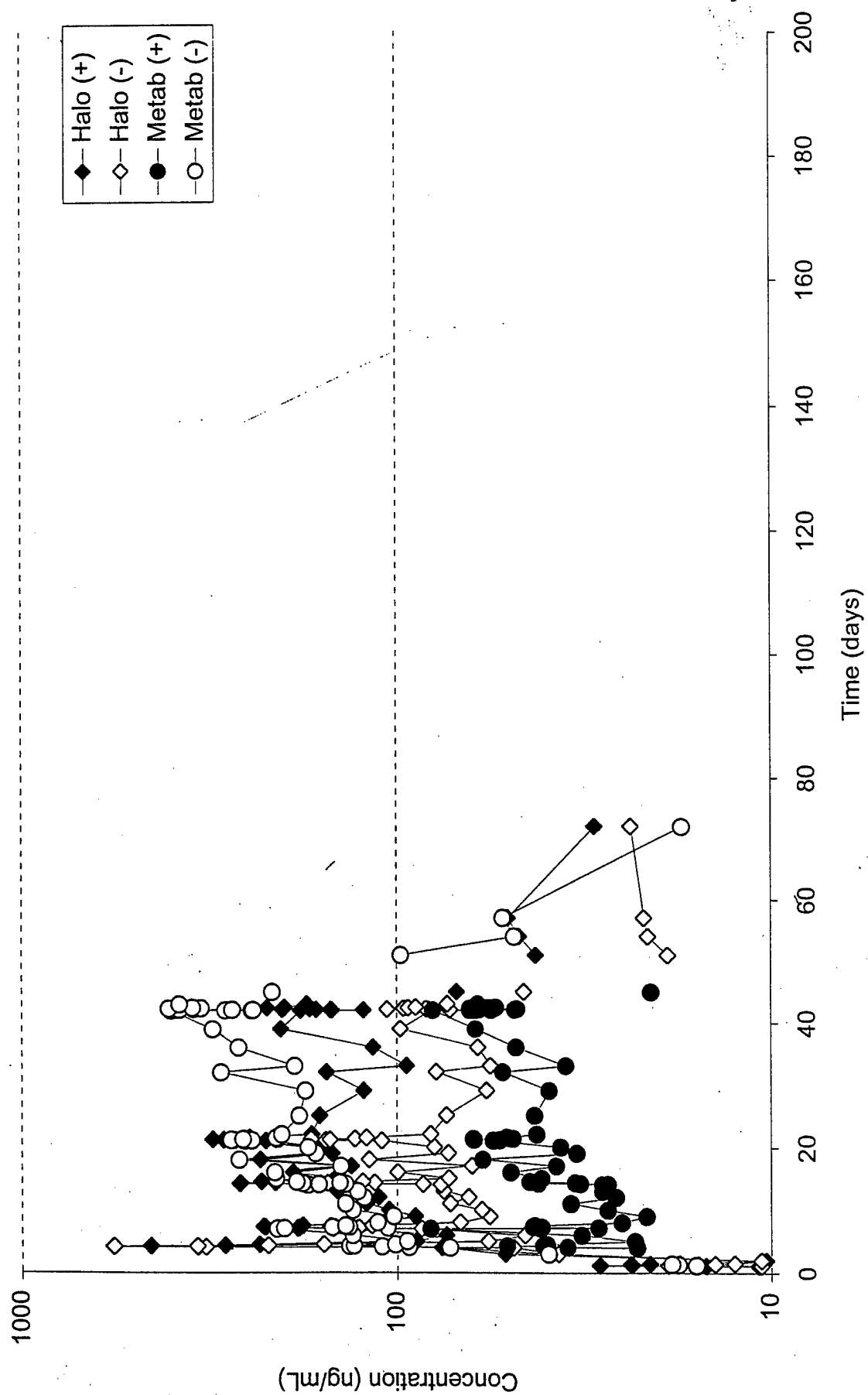


Figure 55f: Halofantrine and Metabolite Concentrations for Subject 08

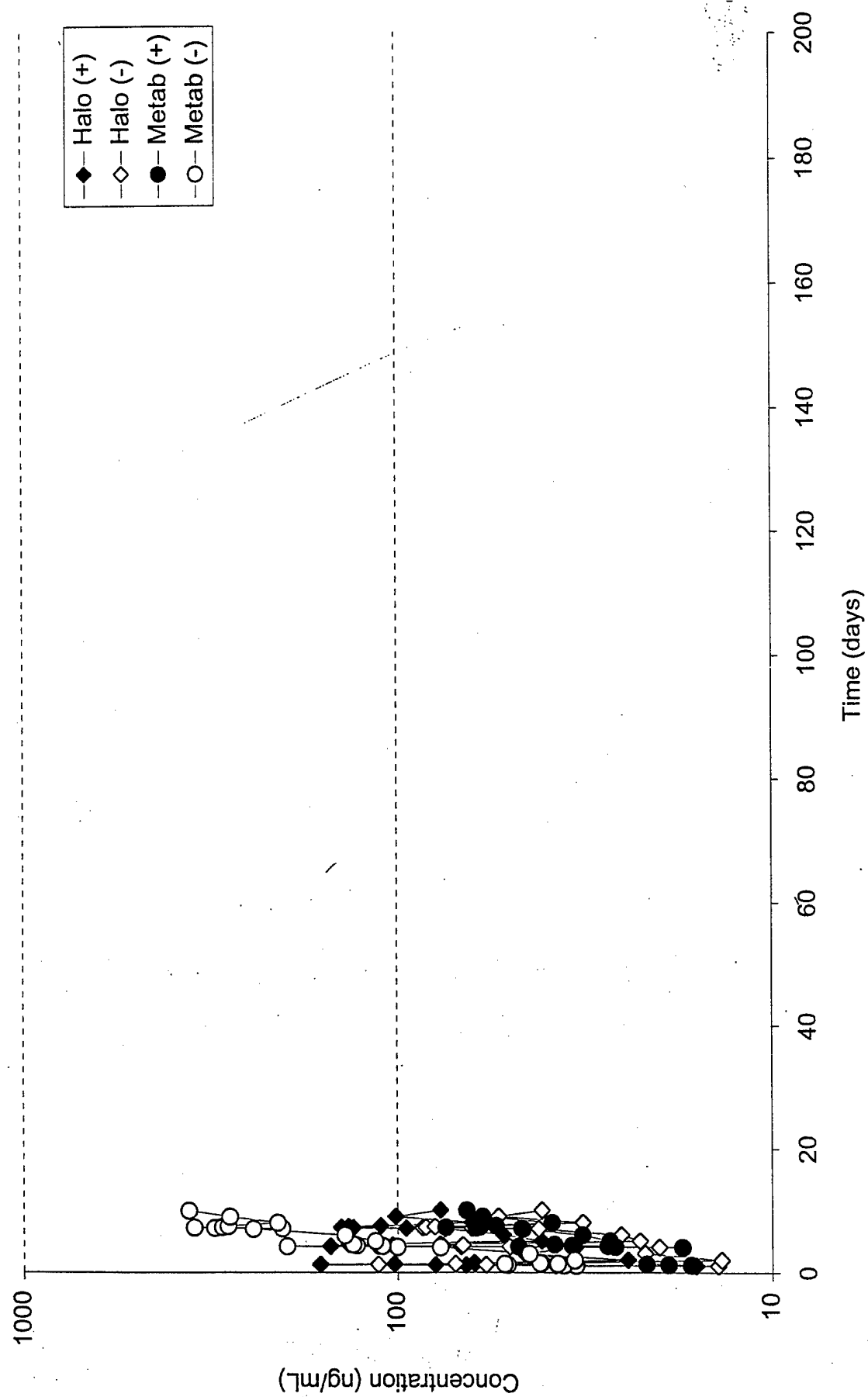


Figure 55g: Halofantrine and Metabolite Concentrations for Subject 09

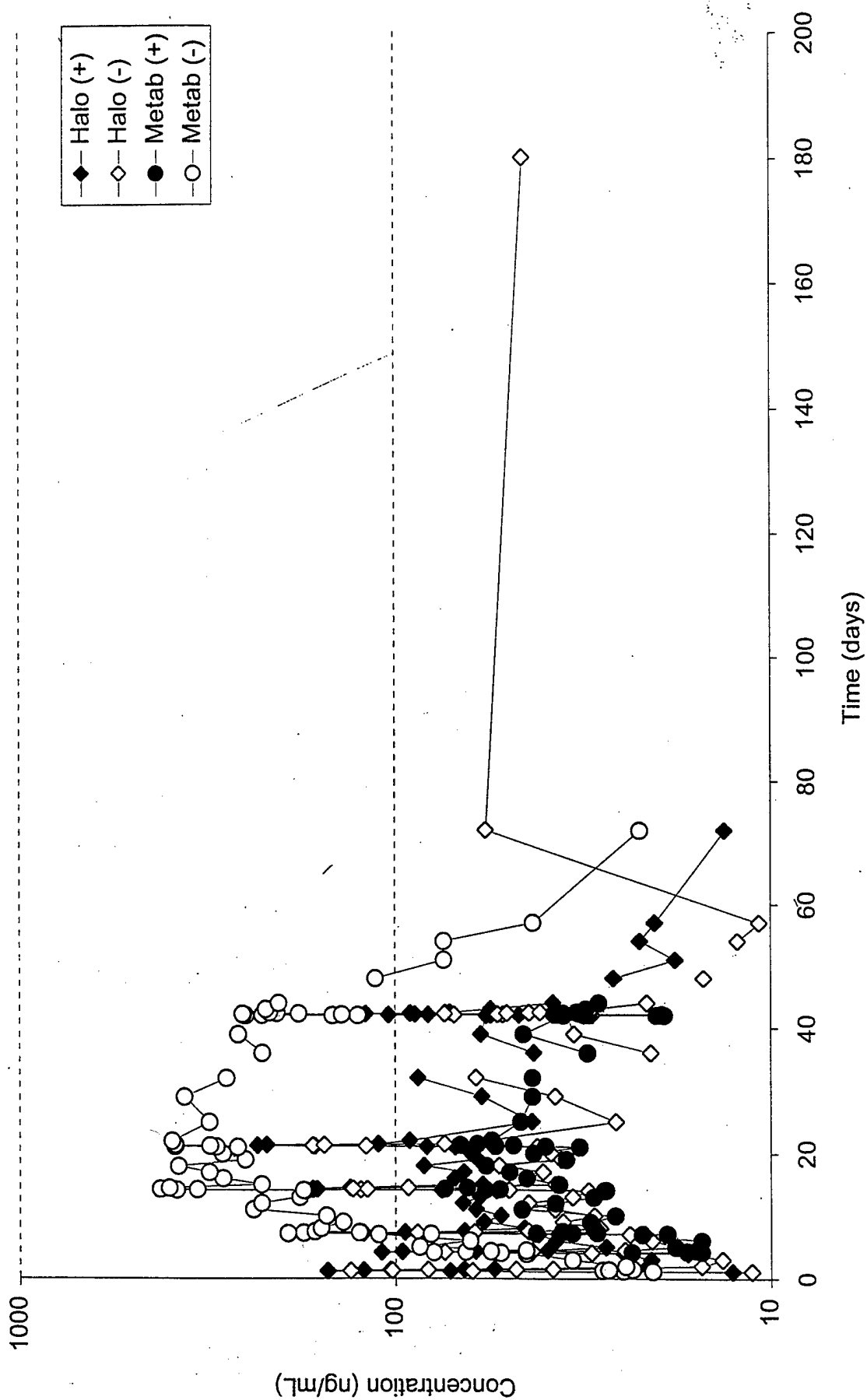


Figure 55h: Halofantrine and Metabolite Concentrations for Subject 10

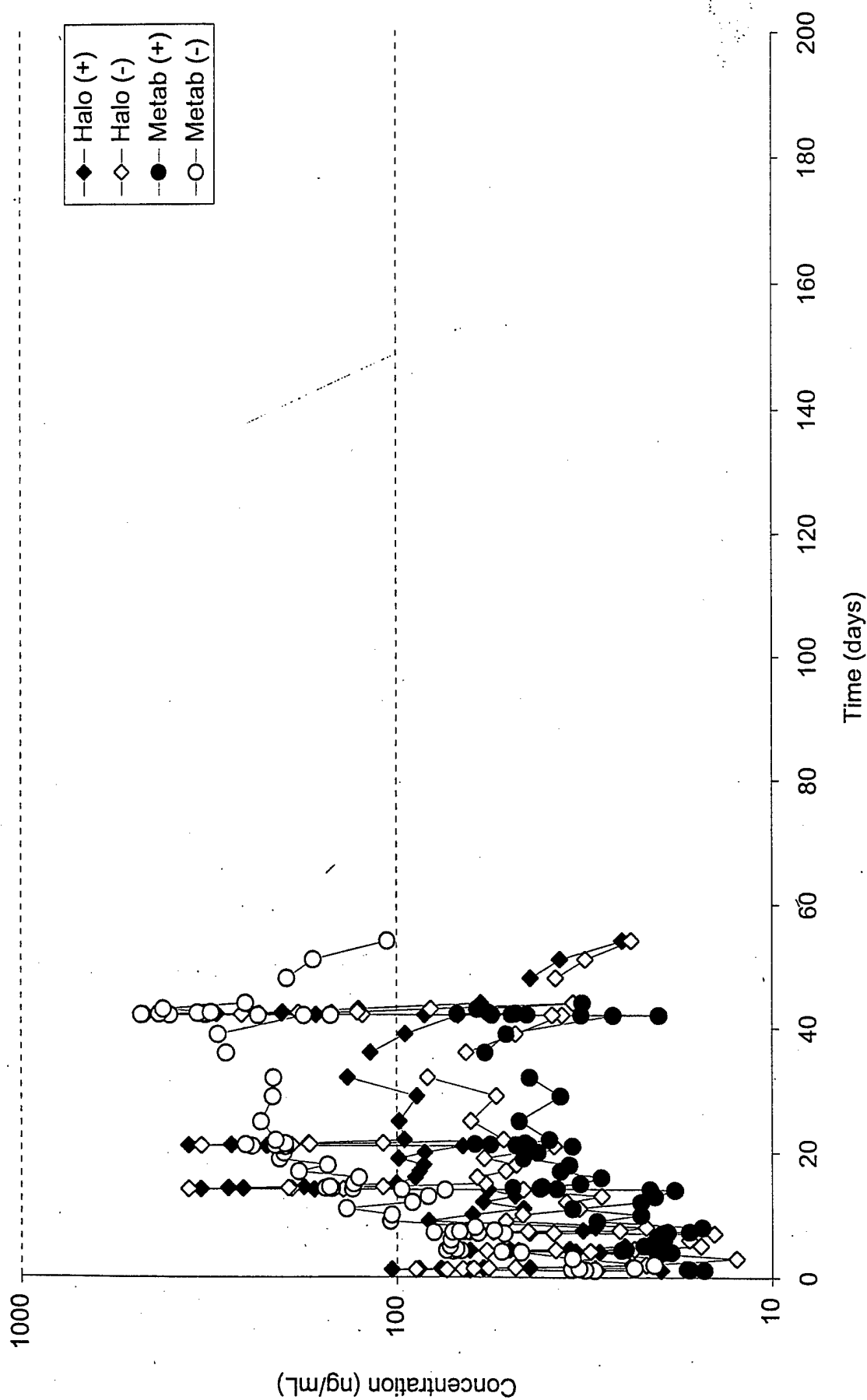


Figure 55I: Halofantrine and Metabolite Concentrations for Subject 11

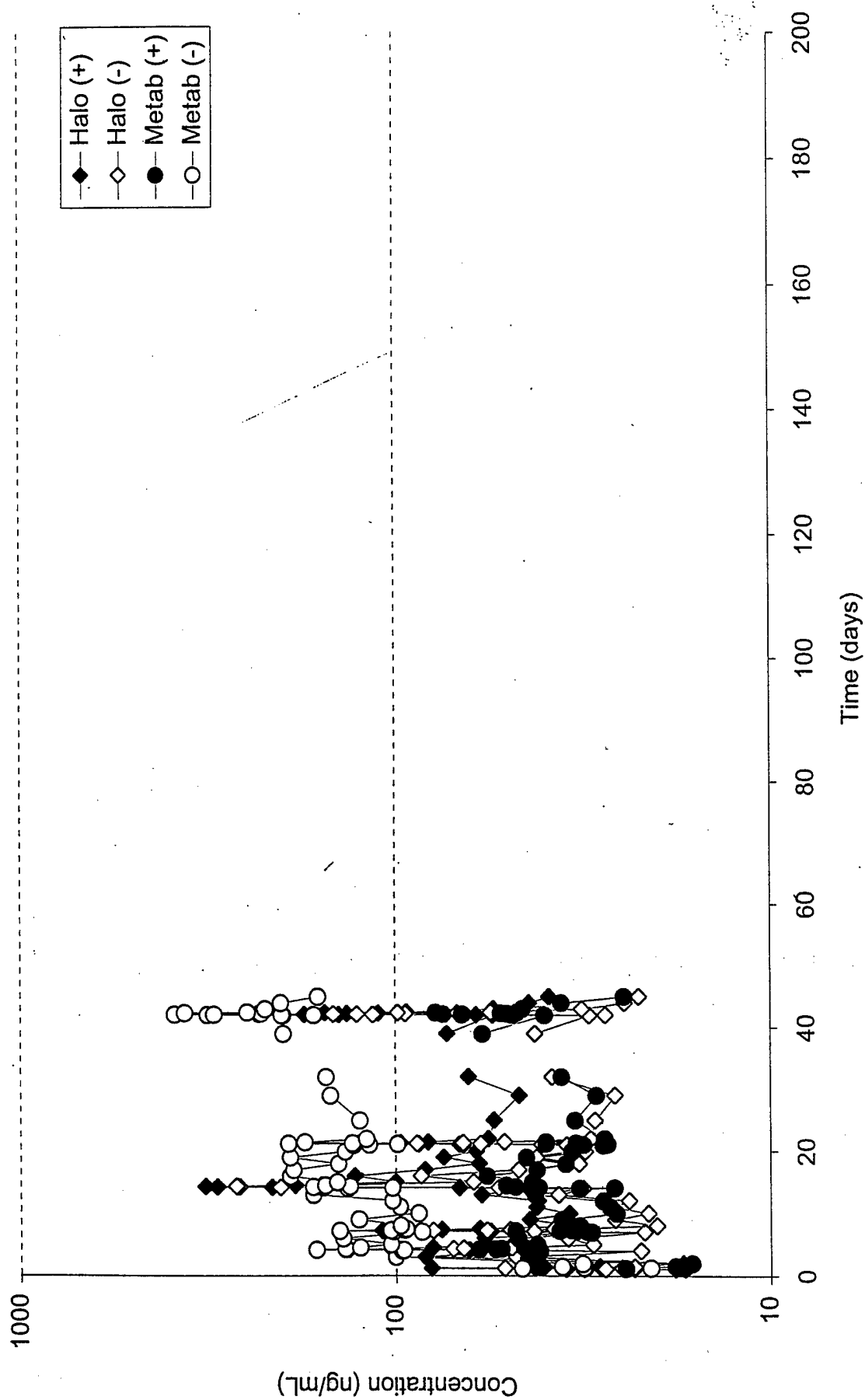


Figure 55j: Halofantrine and Metabolite Concentrations for Subject 14

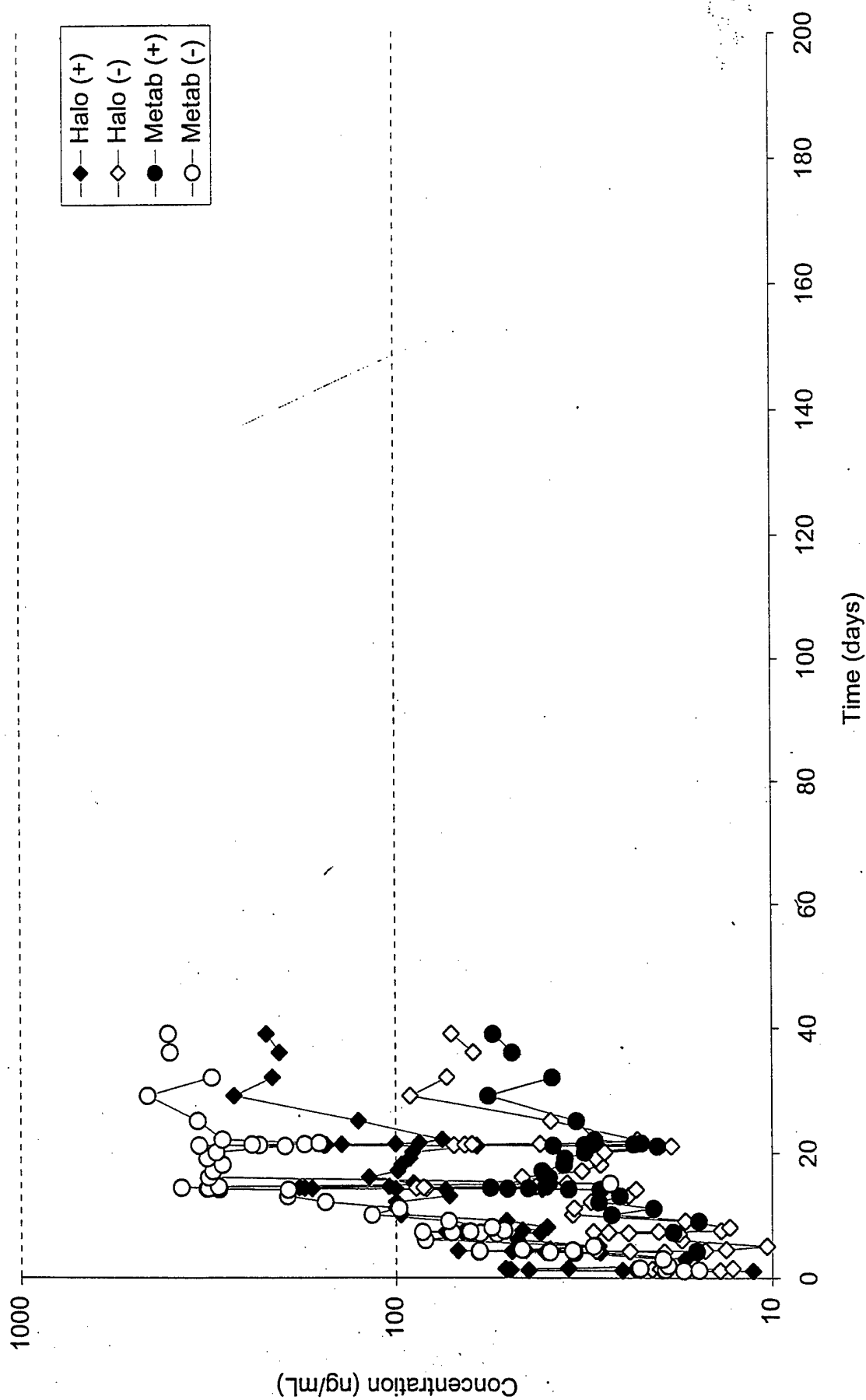




Figure 55k: Halofantrine and Metabolite Concentrations for Subject 15

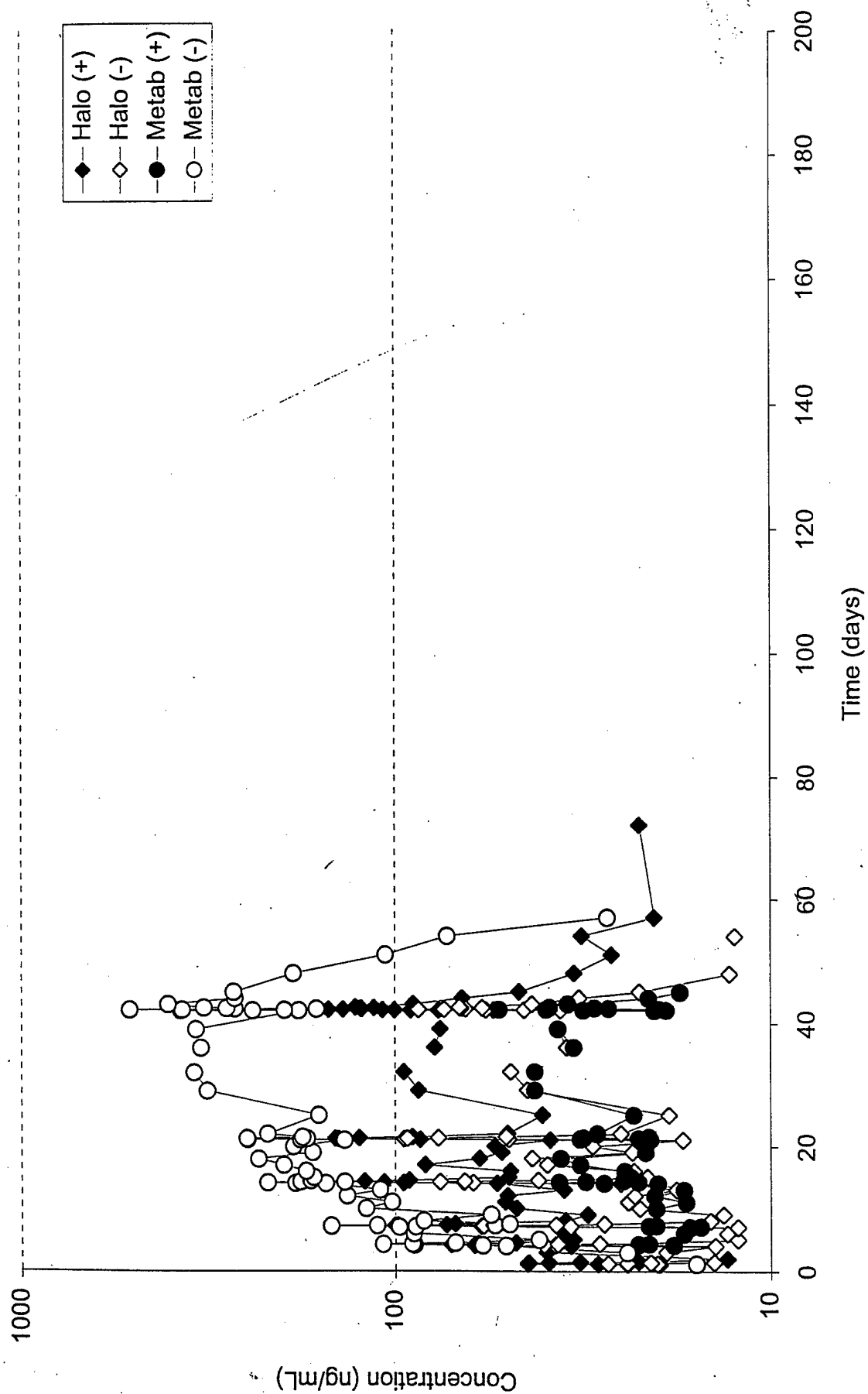


Figure 55L: Halofantrine and Metabolite Concentrations for Subject 16

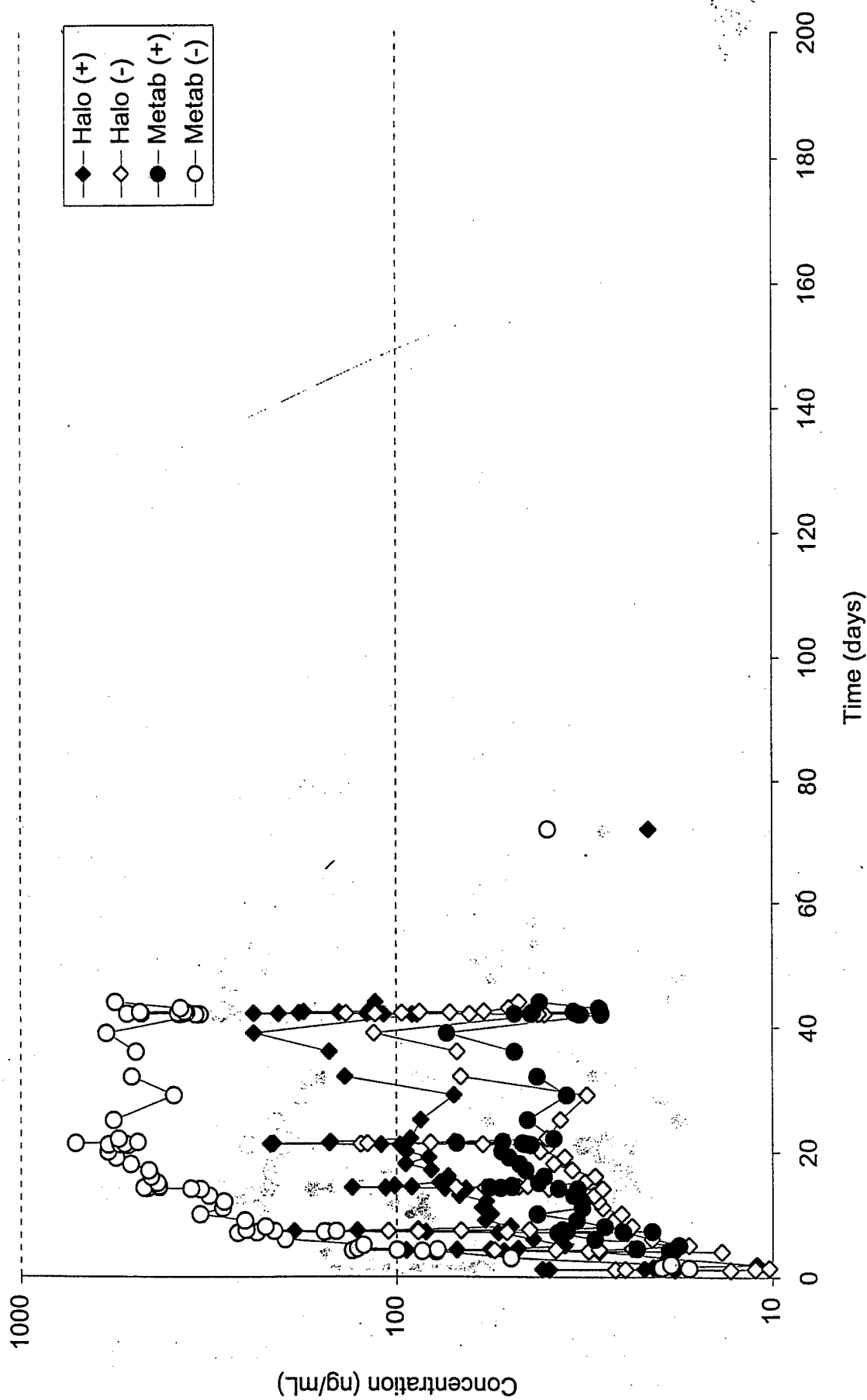


Figure 55n: Halofantrine and Metabolite Concentrations for Subject 19

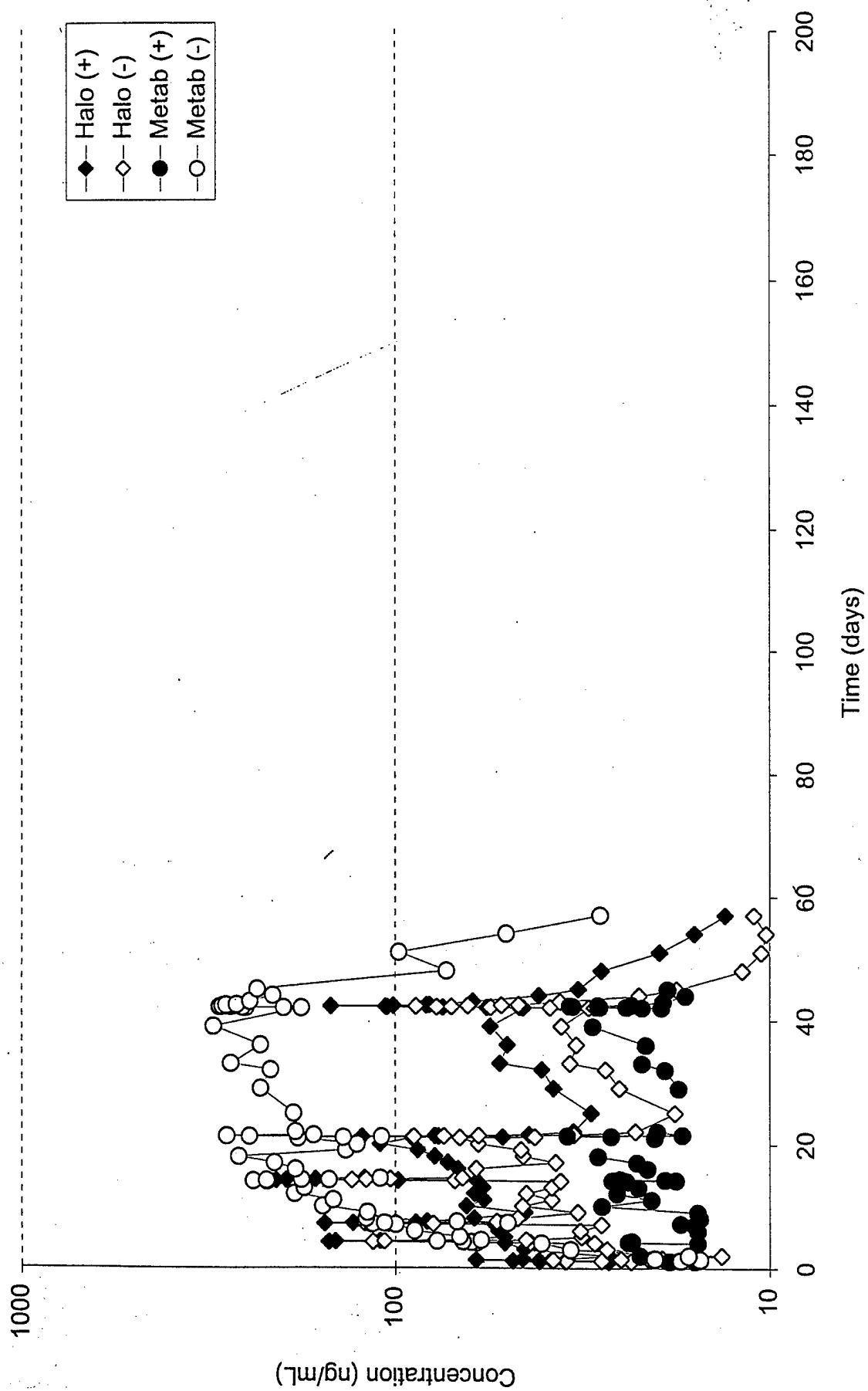


Figure 55o: Halofantrine and Metabolite Concentrations for Subject 20

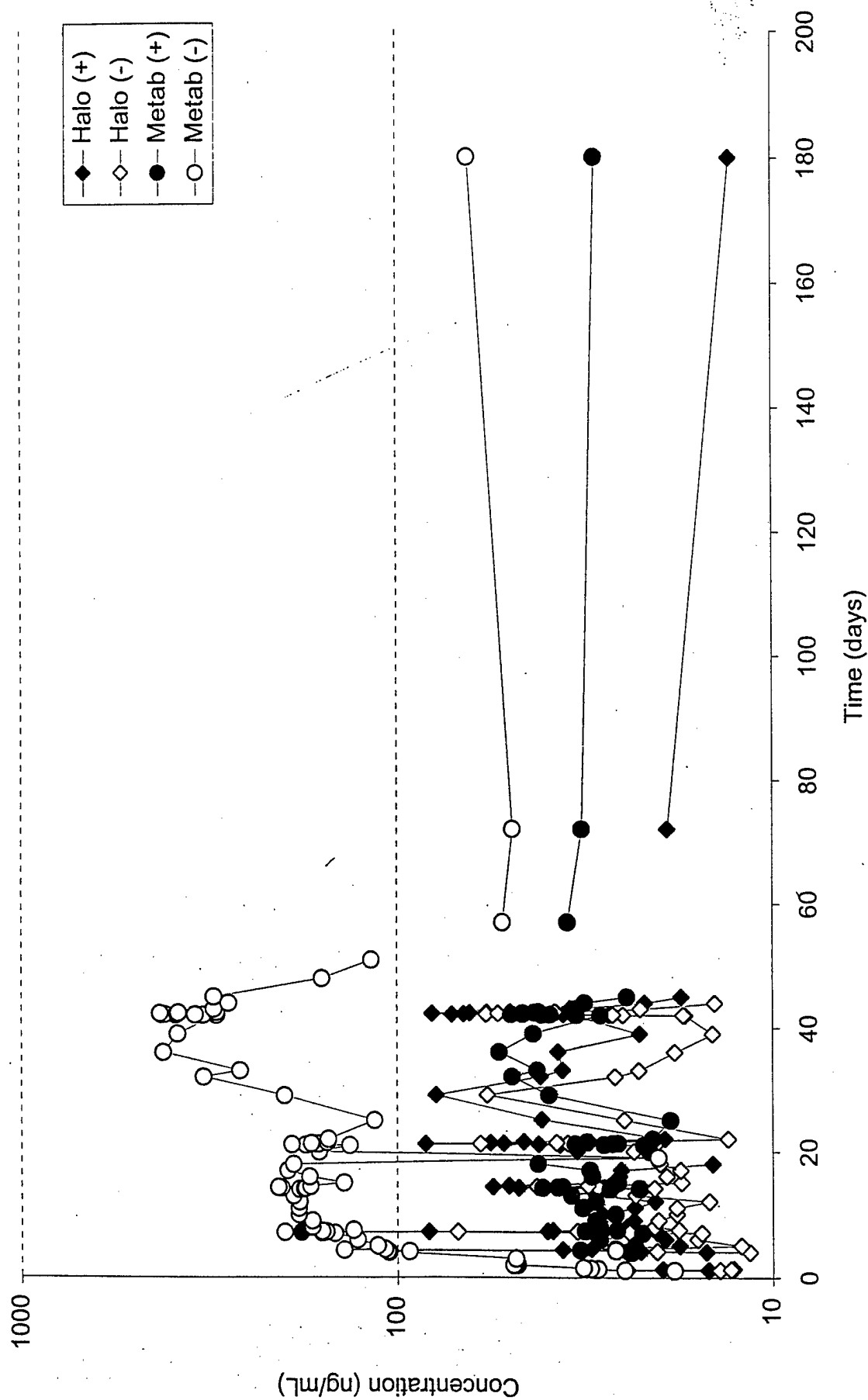
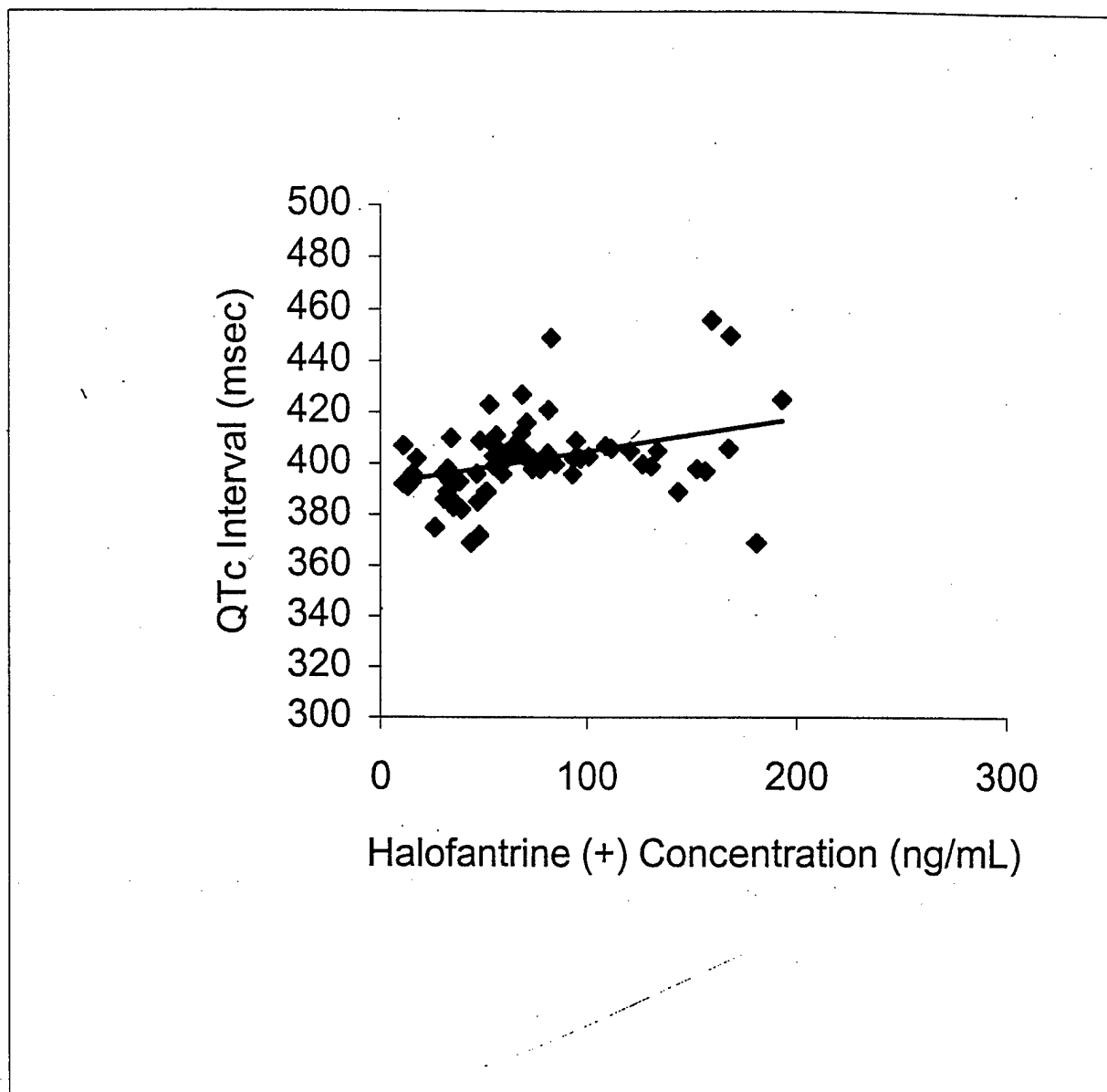


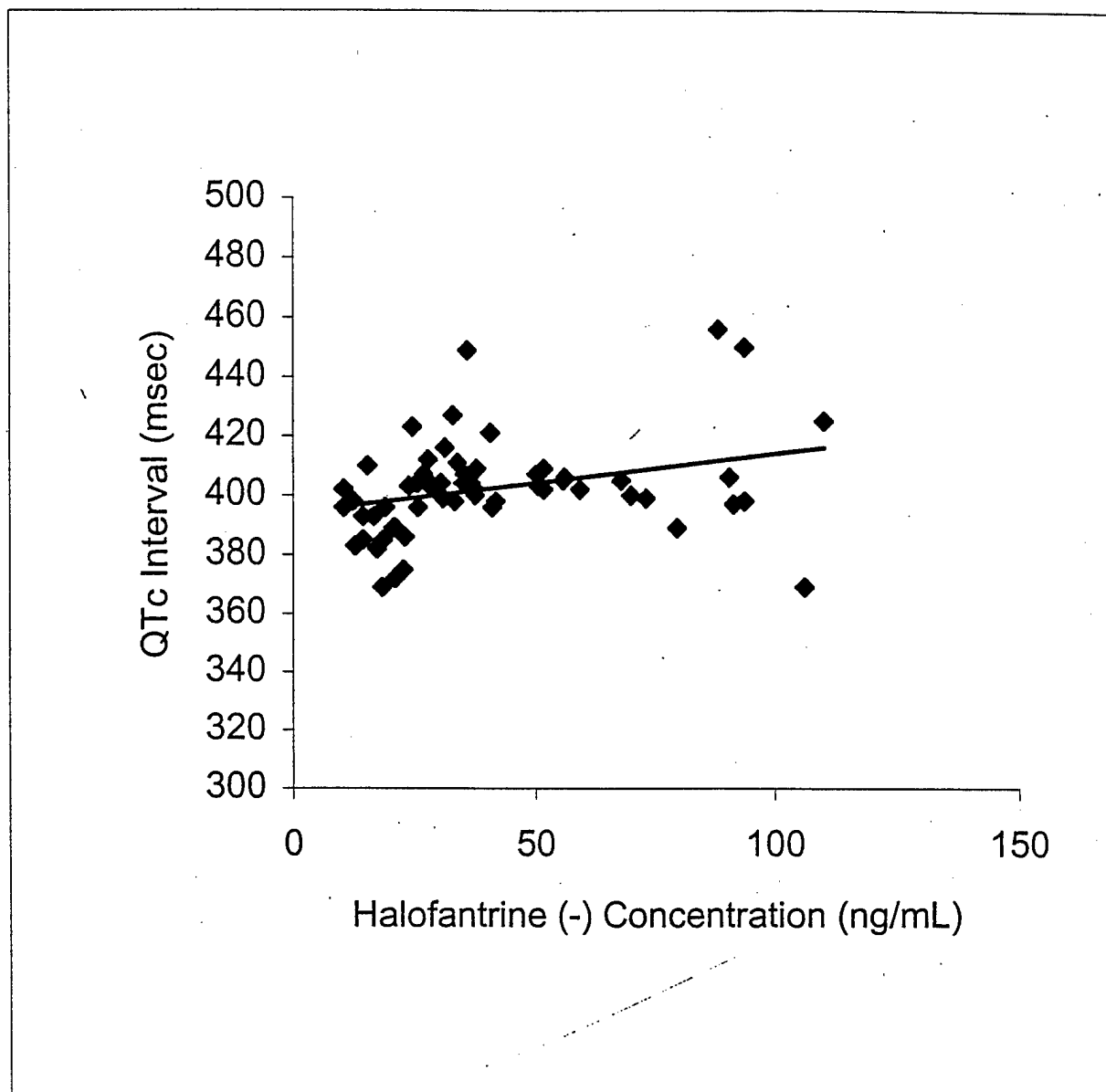
Figure 56a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 01



$$QTc = 392.1 + 0.1281 * Halo(+)$$

$$\text{Correlation Coefficient } (r) = 0.361$$

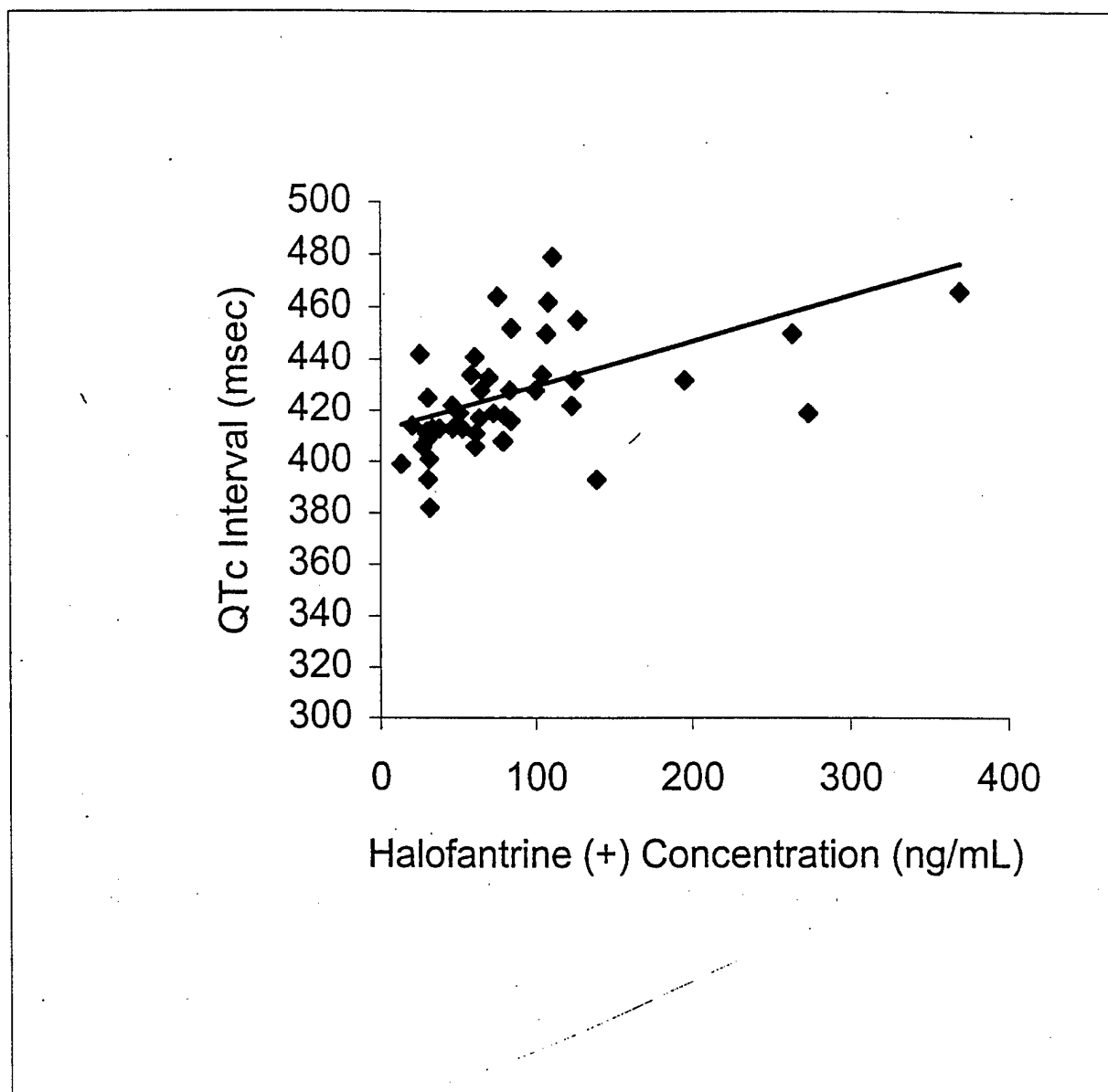
Figure 56b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 01



$$QTc = 394.2 + 0.1979 * Halo(-)$$

Correlation Coefficient (r) = 0.308

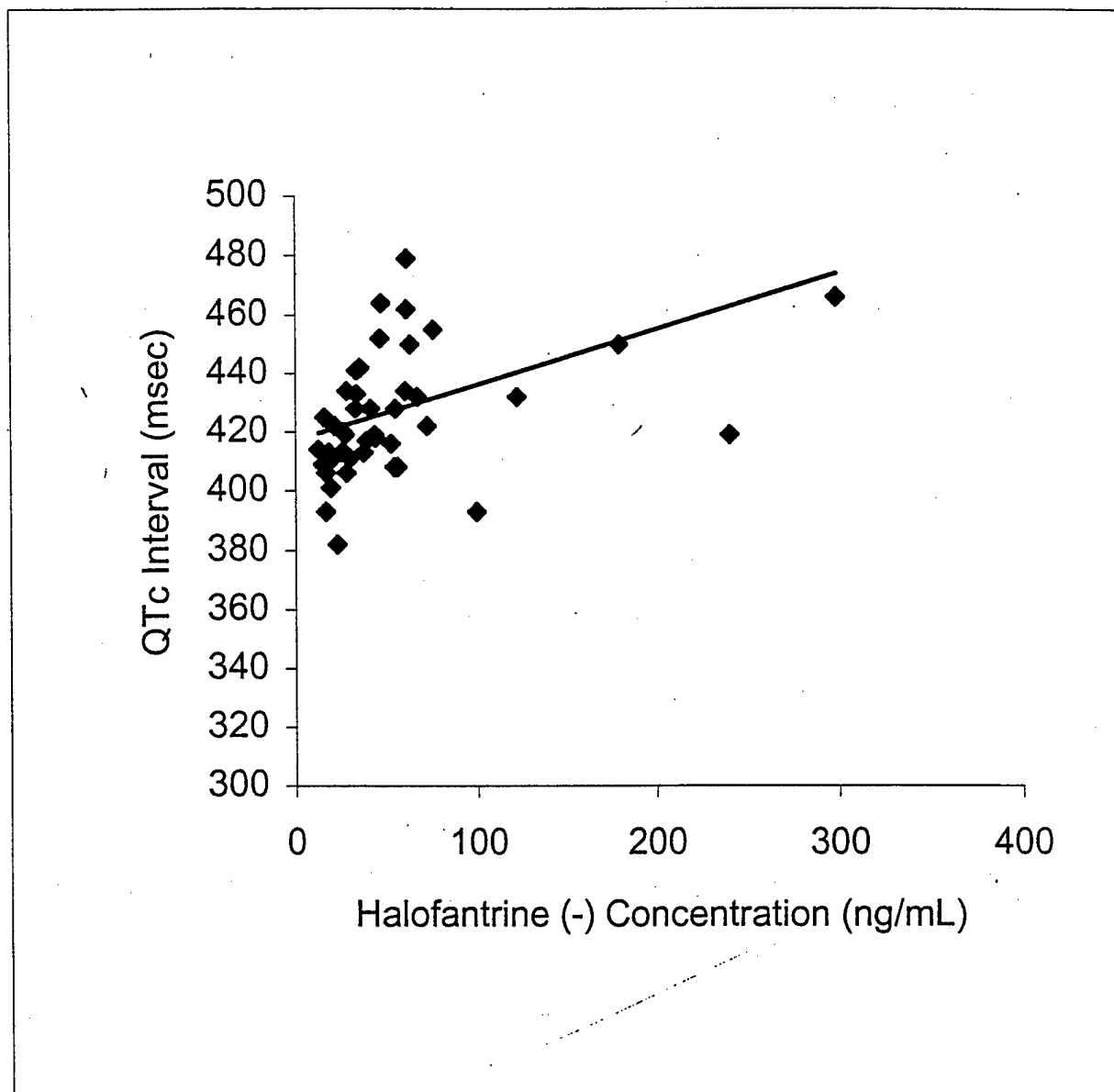
Figure 57a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 02



$$QTc = 412.2 + 0.1748 * Halo(+)$$

$$\text{Correlation Coefficient } (r) = 0.511$$

Figure 57b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 02

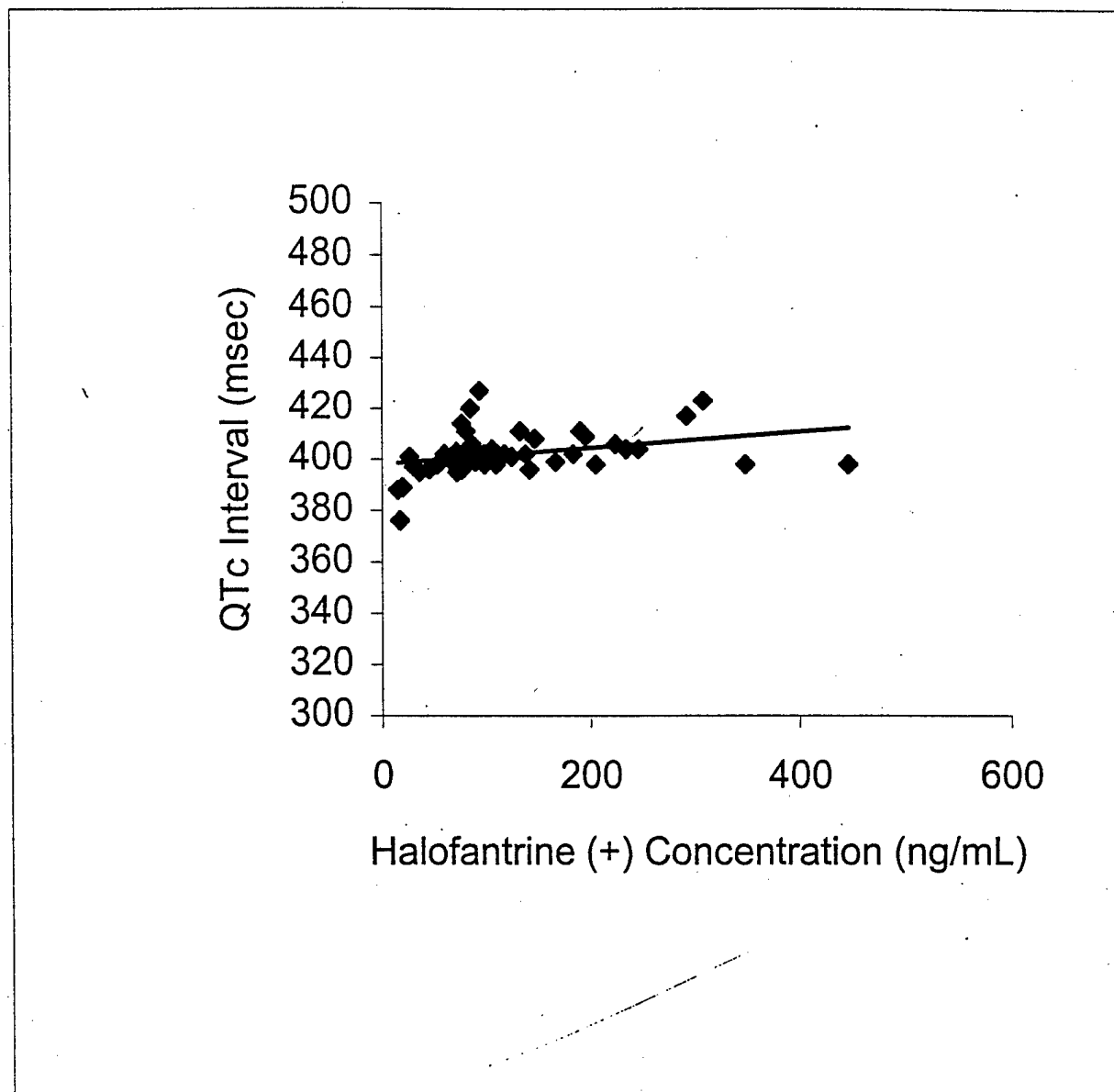


$$QTc = 417.2 + 0.1904 * Halo(-)$$

Correlation Coefficient (r) = 0.447



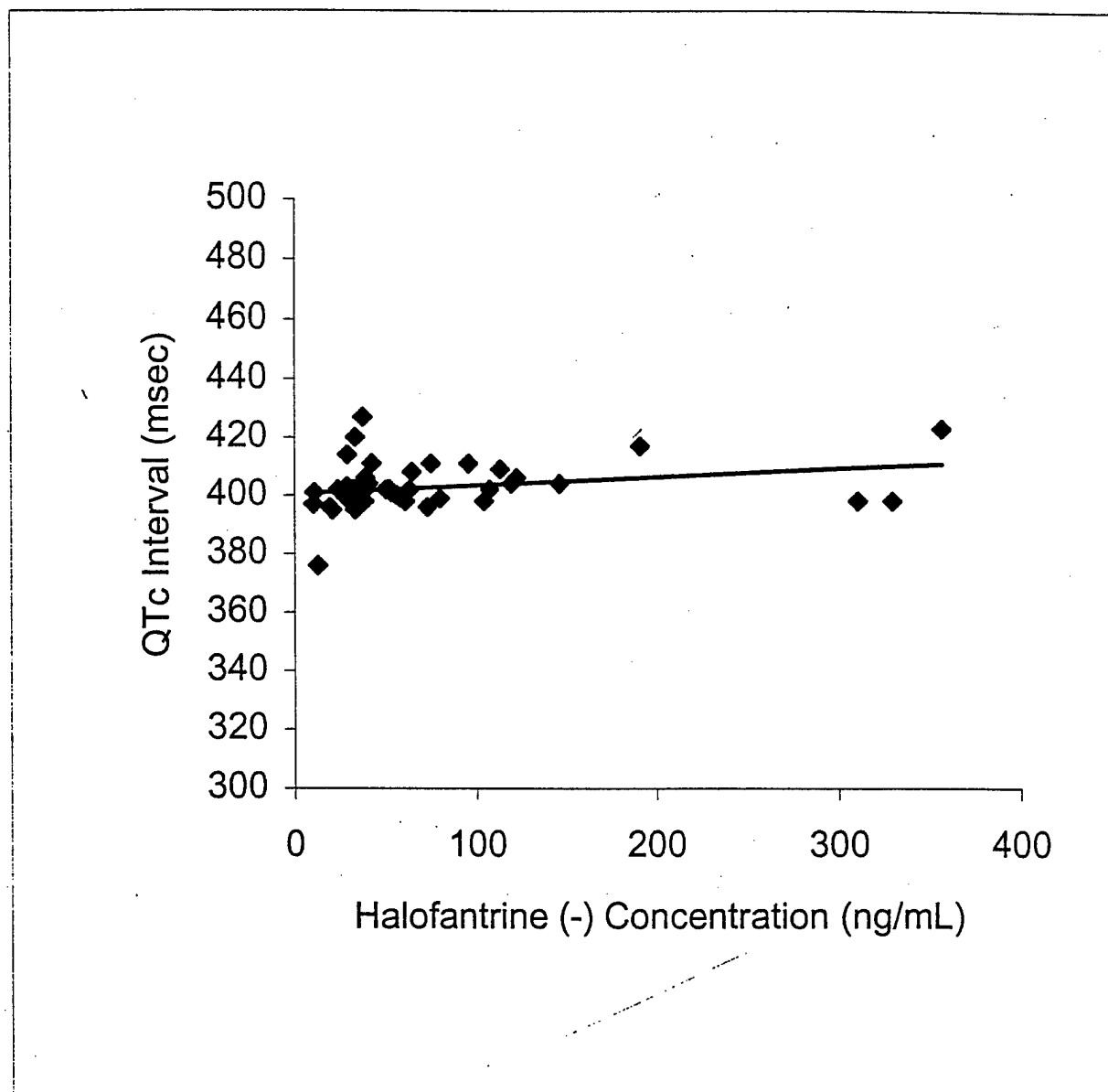
Figure 58a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 04



$$QTc = 398.2 + 0.0318 * Halo(+)$$

Correlation Coefficient (r) = 0.334

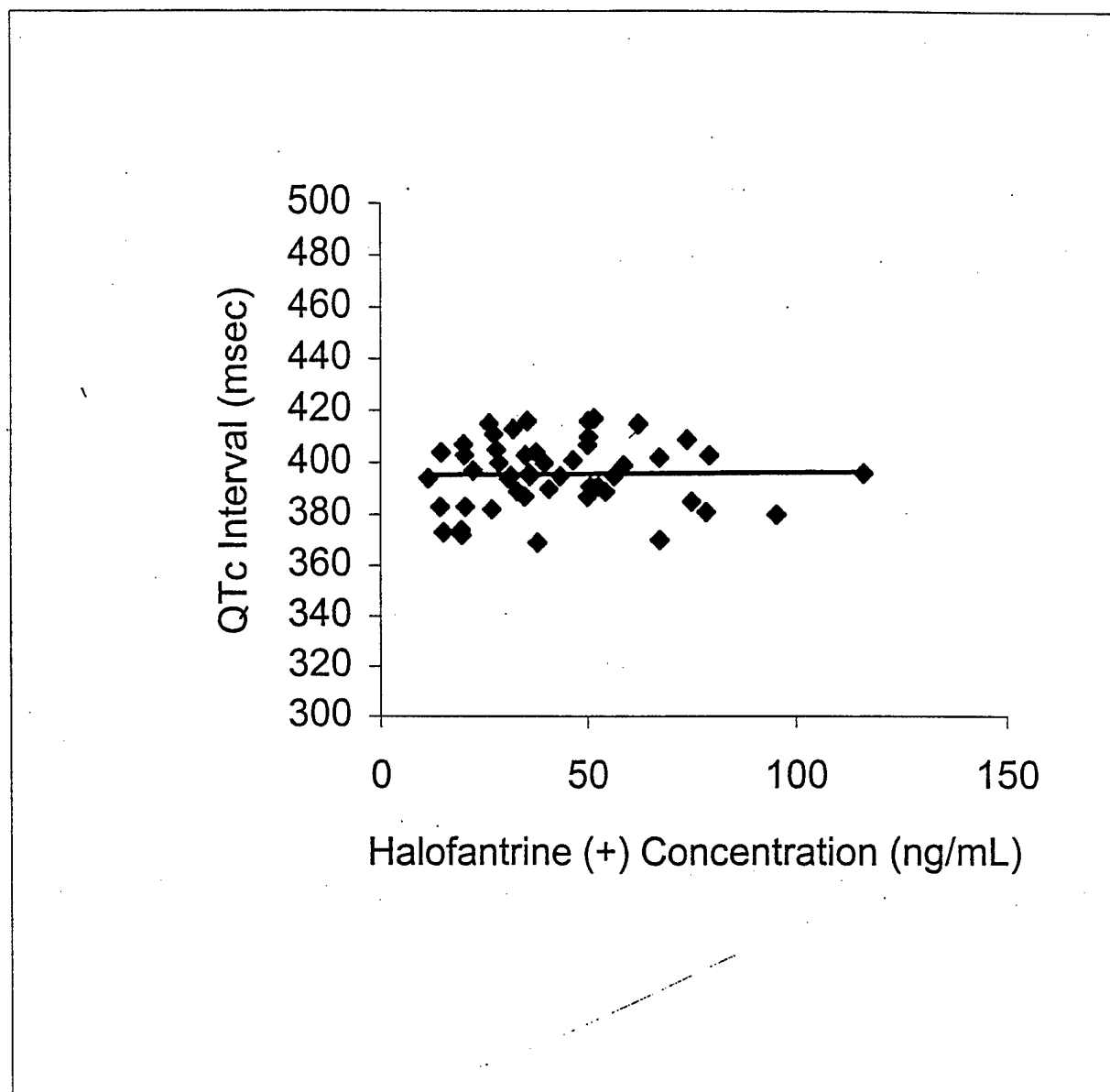
Figure 58b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 04



$$QTc = 400.6 + 0.0287 * Halo(-)$$

$$\text{Correlation Coefficient (r)} = 0.272$$

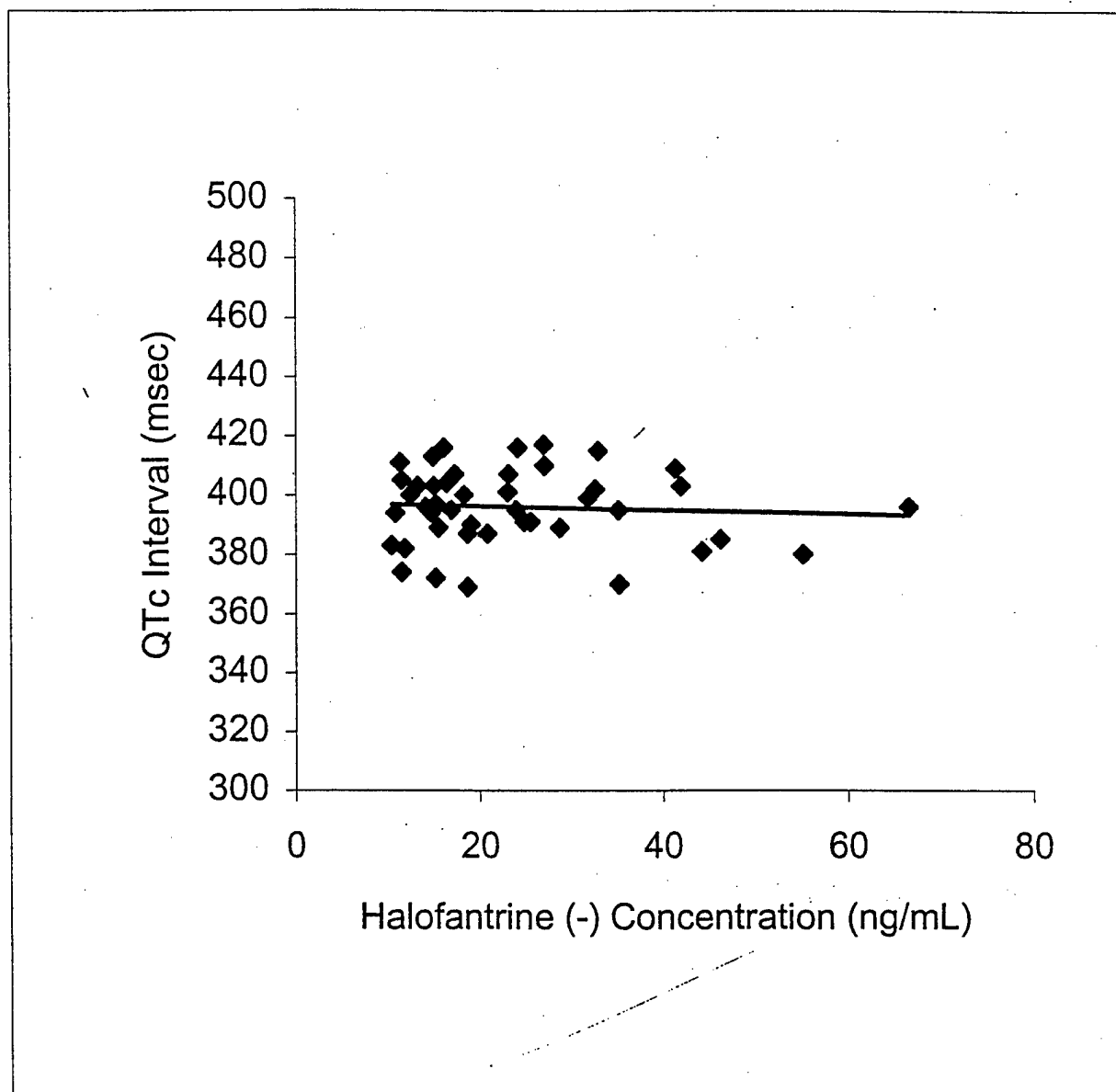
Figure 59a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 05



$$QTc = 395.3 + 0.0119 * Halo(+)$$

$$\text{Correlation Coefficient } (r) = 0.021$$

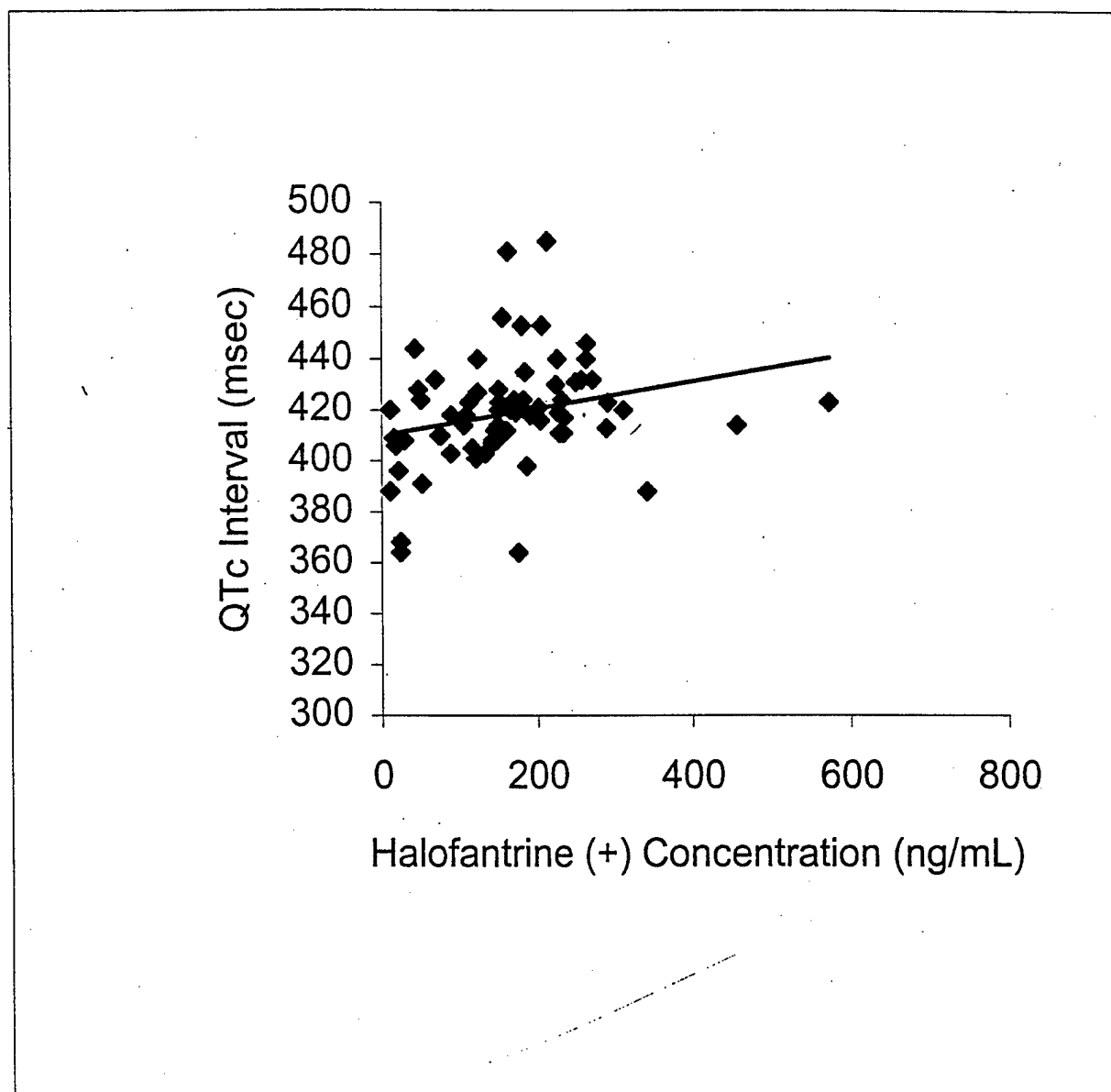
Figure 59b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 05



$$QTc = 397.5 + -0.0663 * Halo(-)$$

$$\text{Correlation Coefficient (r)} = -0.067$$

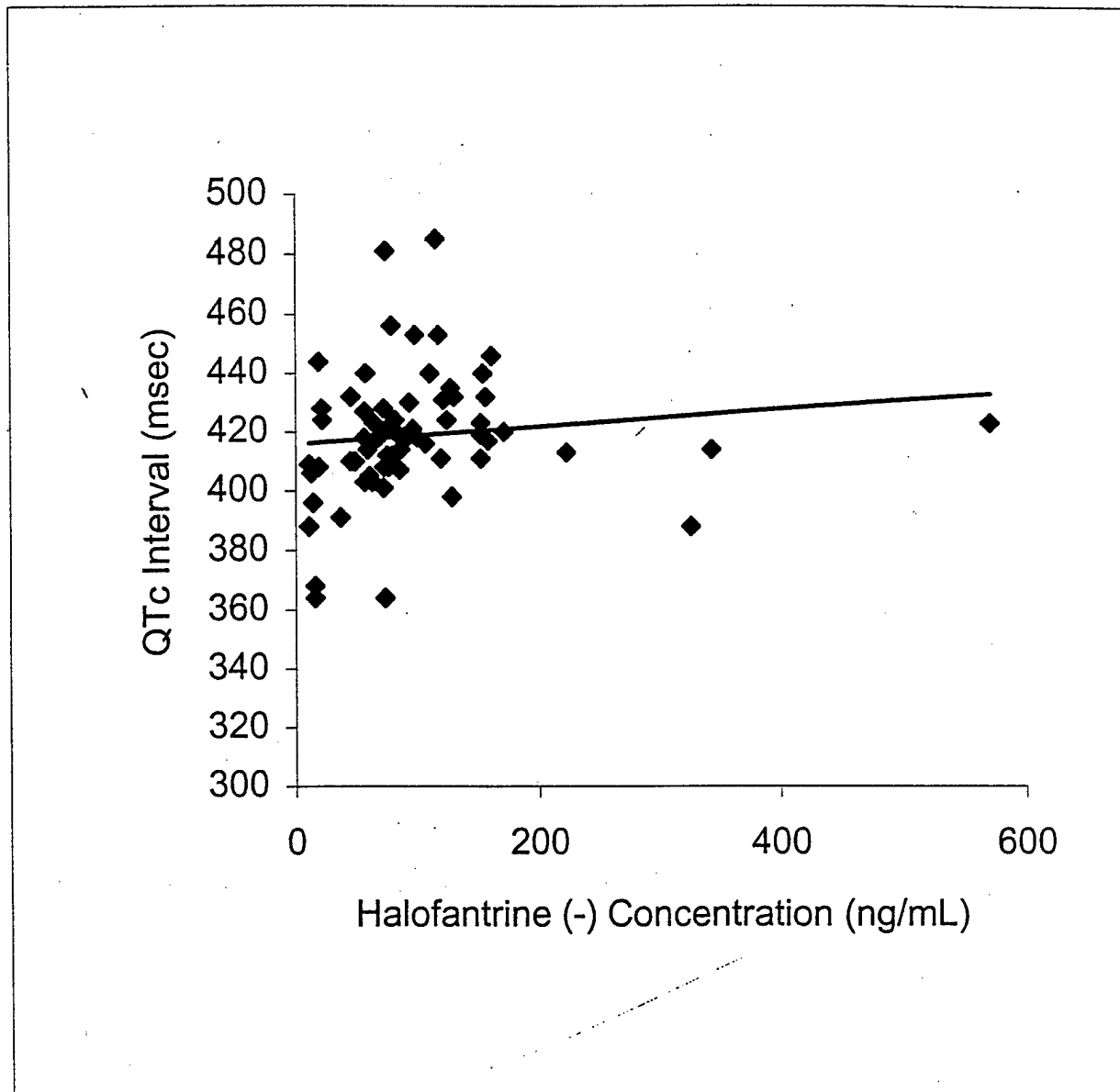
Figure 60a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 07



$$QTc = 410.1 + 0.0531 * Halo(+)$$

Correlation Coefficient (r) = 0.255

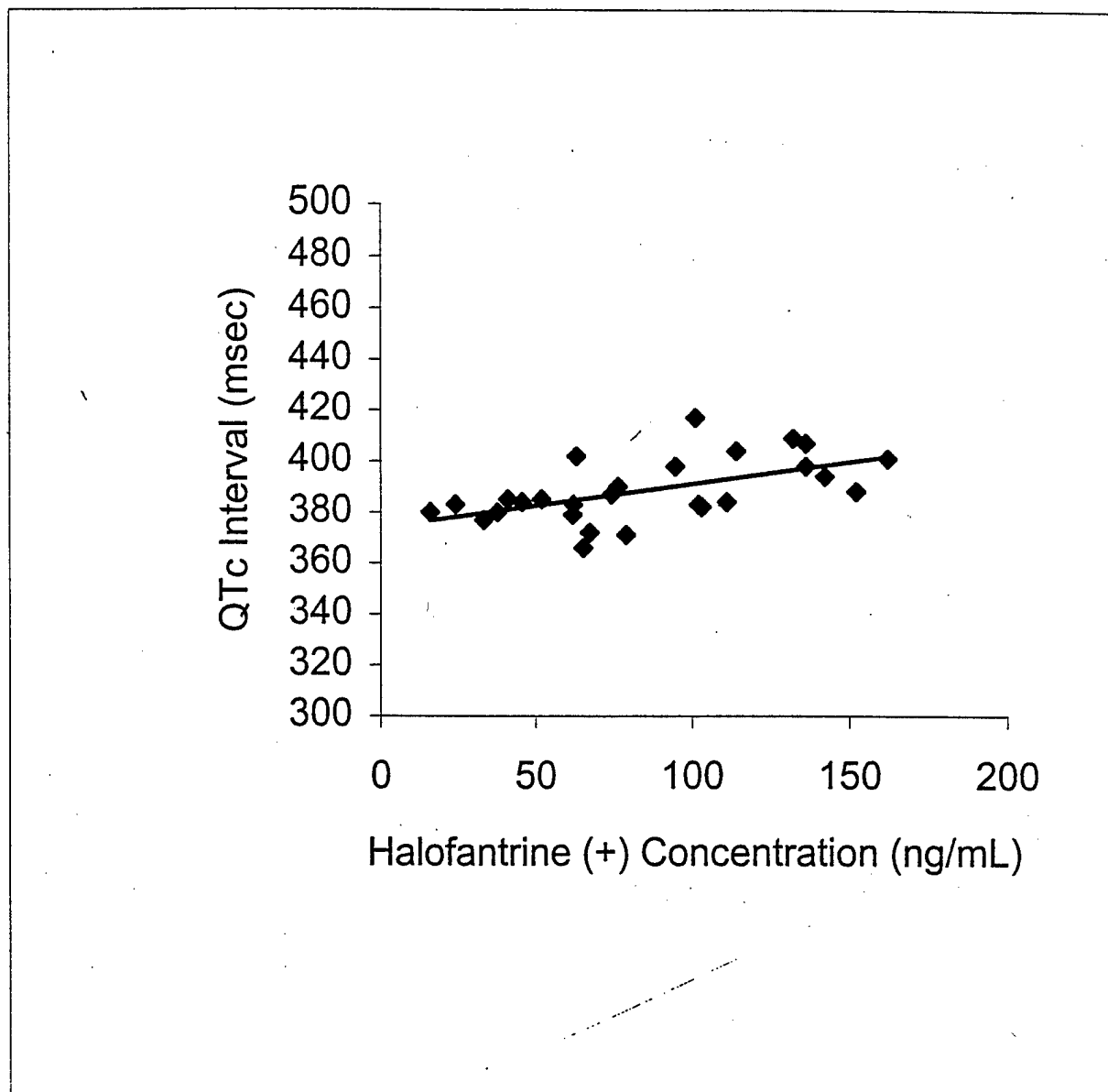
Figure 60b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 07



$$QTc = 415.8 + 0.0301 * Halo(-)$$

Correlation Coefficient (r) = 0.120

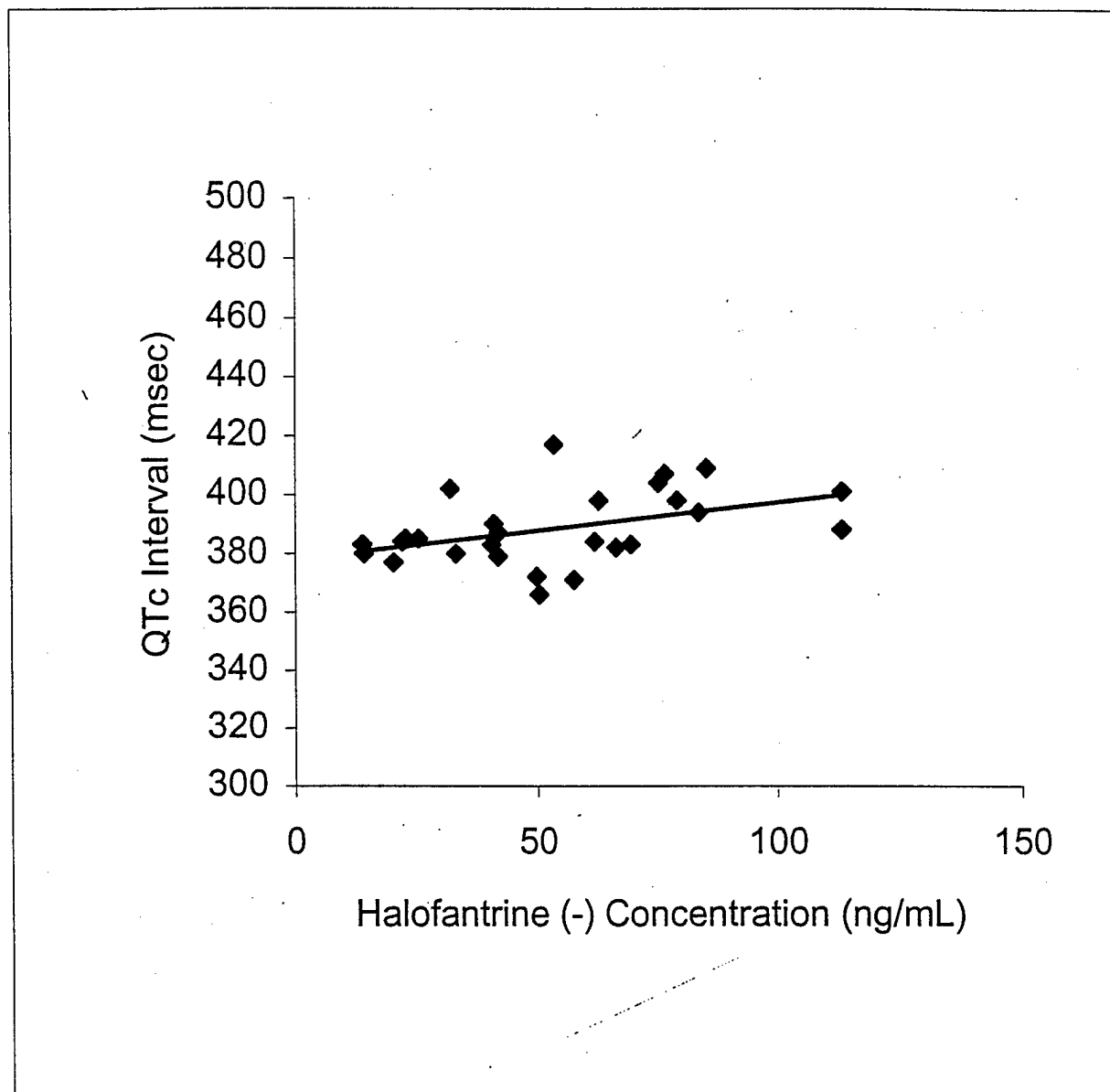
Figure 61a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 08



$$QTc = 373.9 + 0.1718 * Halo(+)$$

Correlation Coefficient (r) = 0.569

Figure 61b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 08

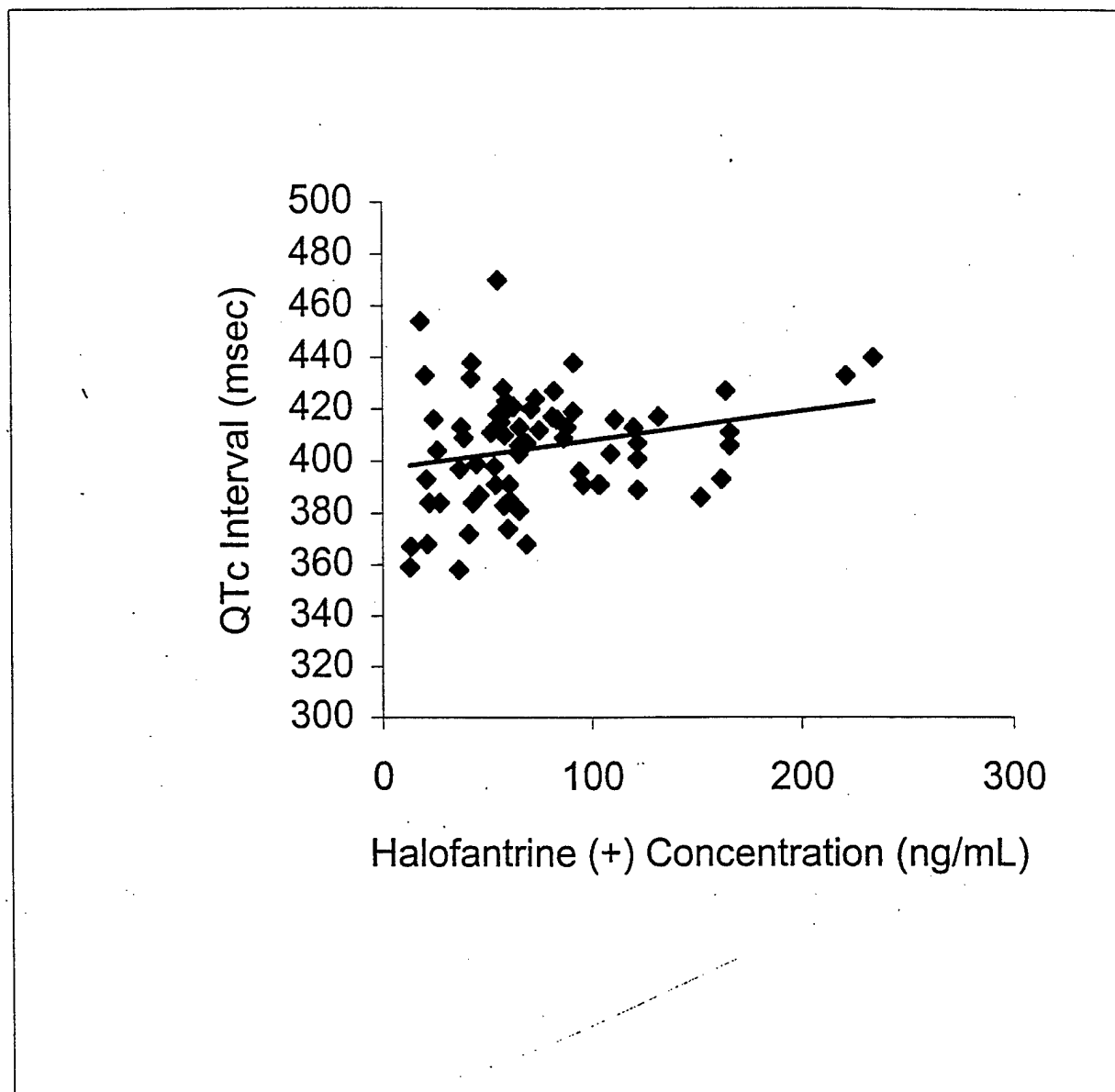


$$QTc = 378.2 + 0.1927 * Halo(-)$$

Correlation Coefficient (r) = 0.429



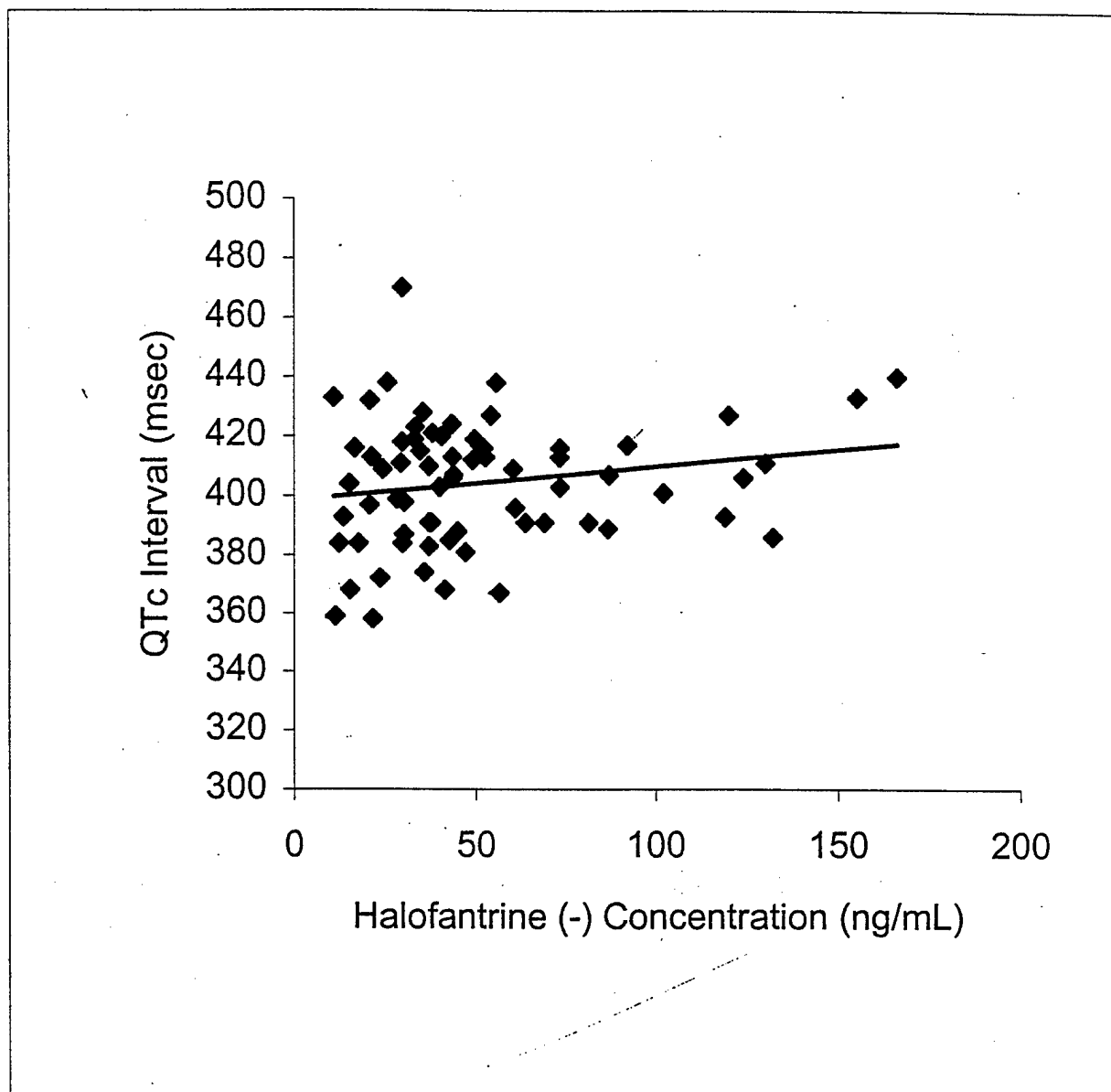
Figure 62a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 09



$$QTc = 397.1 + 0.1109 * Halo(+)$$

Correlation Coefficient (r) = 0.238

Figure 62b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 09



$$QTc = 398.6 + 0.1130 * Halo(-)$$

$$\text{Correlation Coefficient } (r) = 0.189$$

Figure 63a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 10

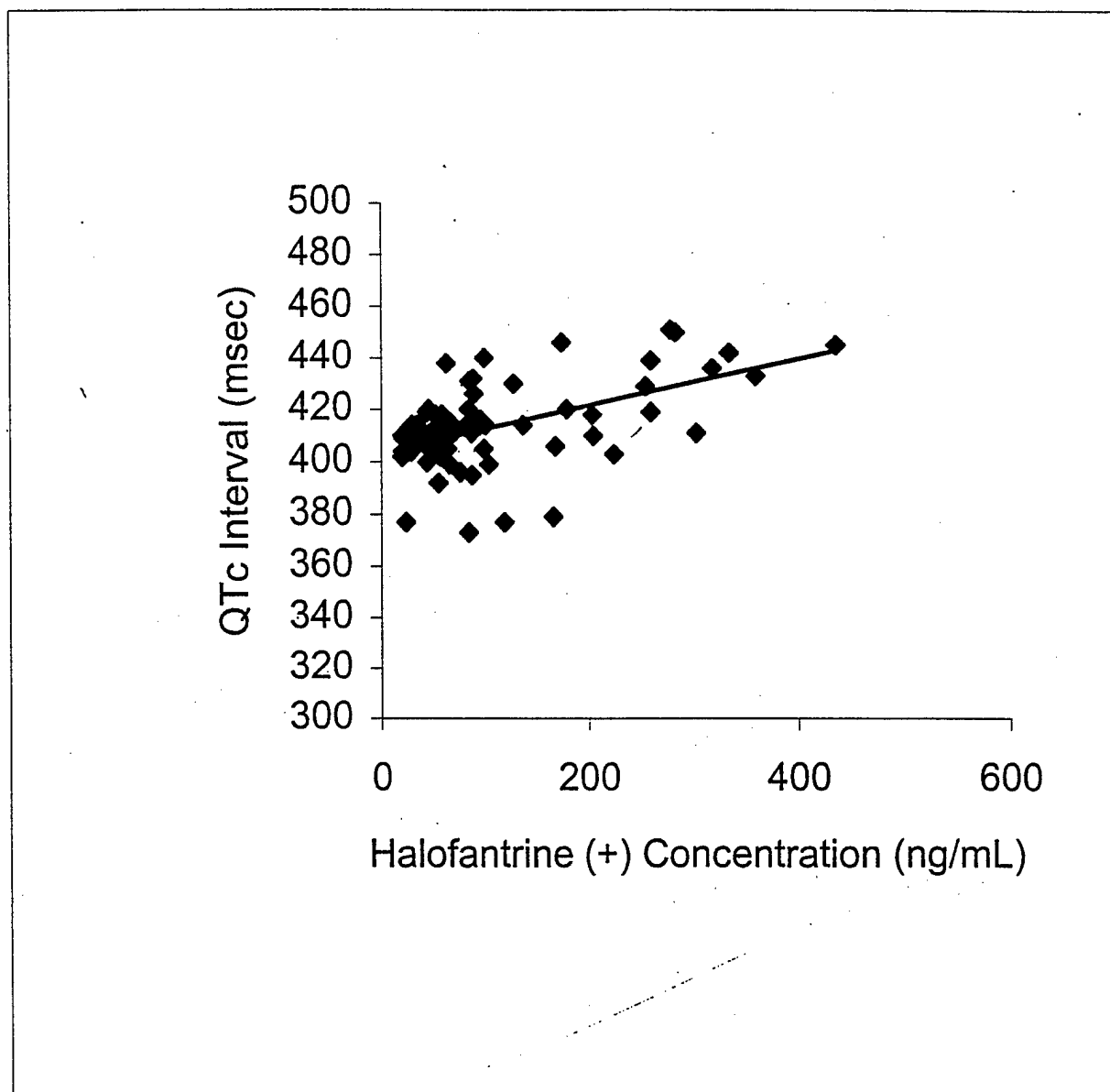
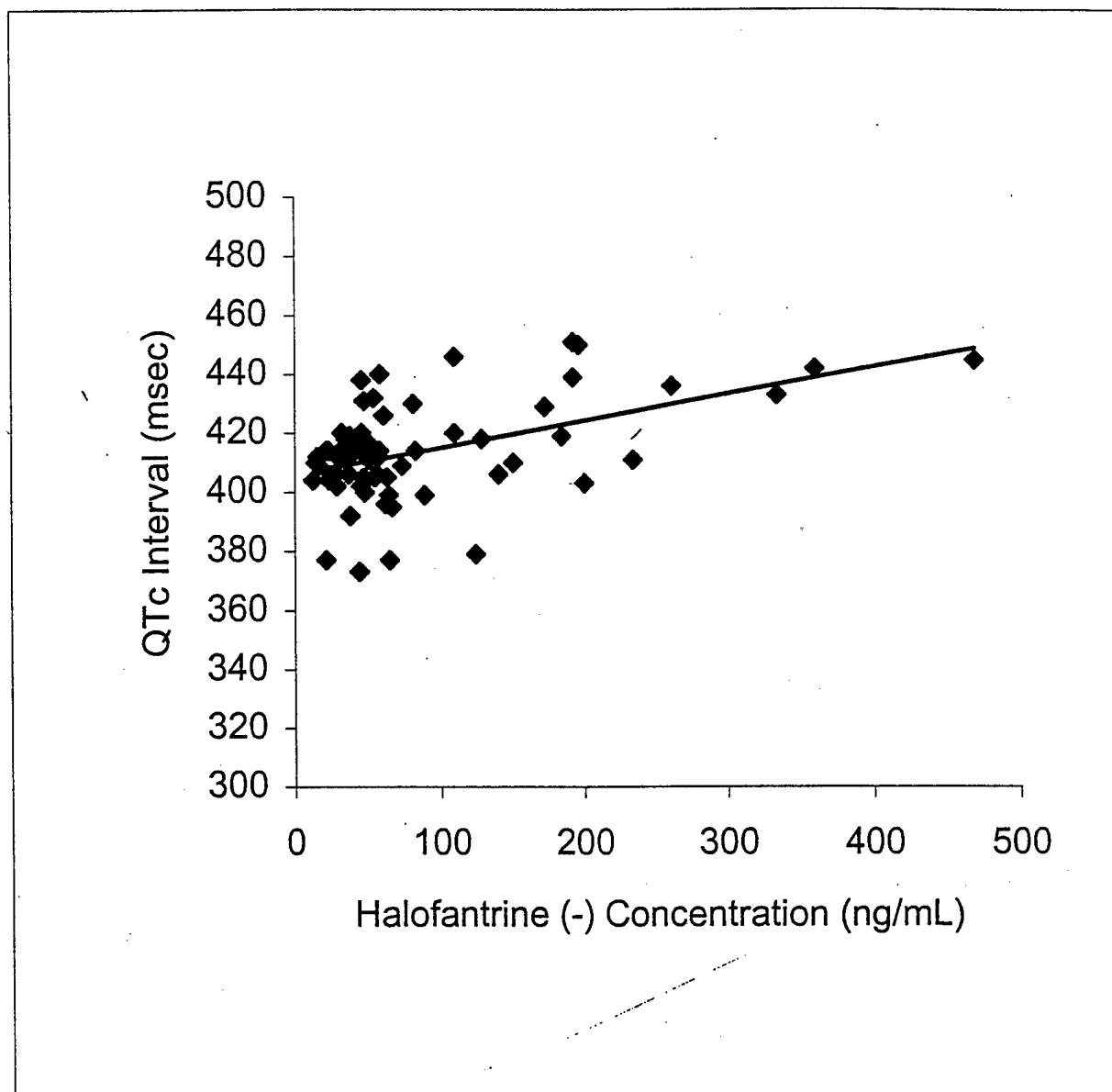


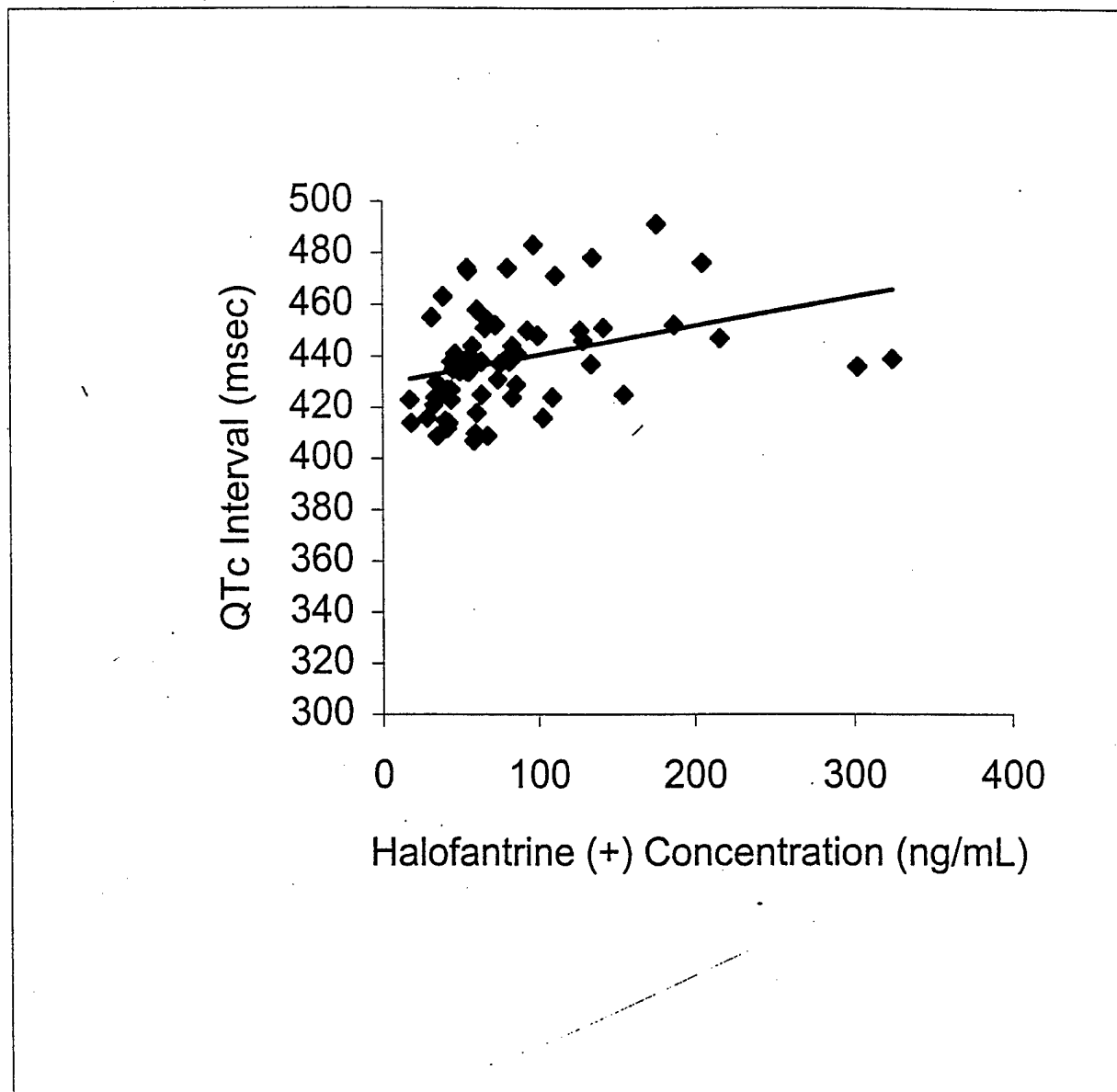
Figure 63b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 10



$$QTc = 405.9 + 0.0920 * Halo(-)$$

Correlation Coefficient (r) = 0.487

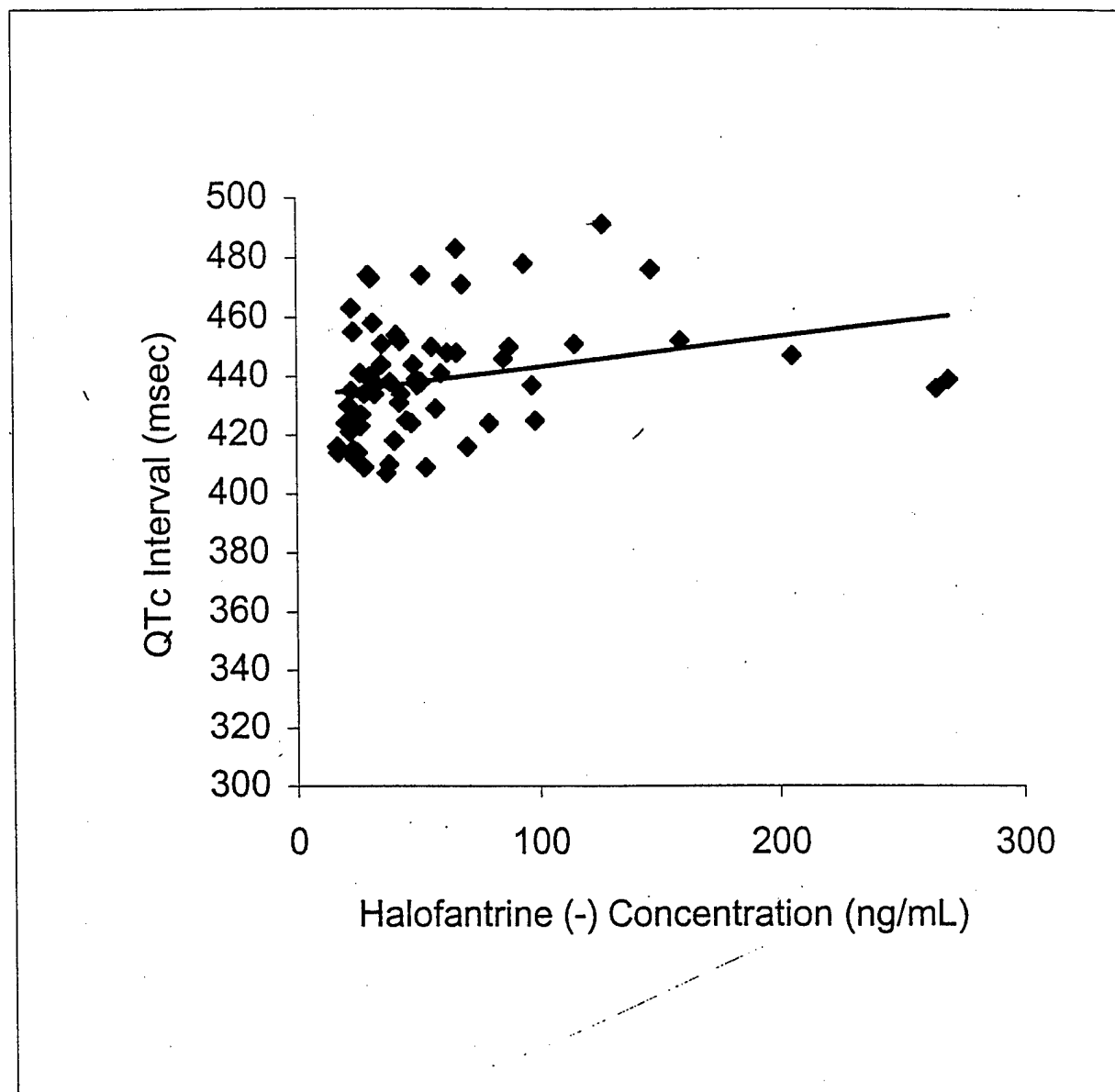
Figure 64a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 11



$$QTc = 429.4 + 0.1126 * Halo(+)$$

Correlation Coefficient (r) = 0.339

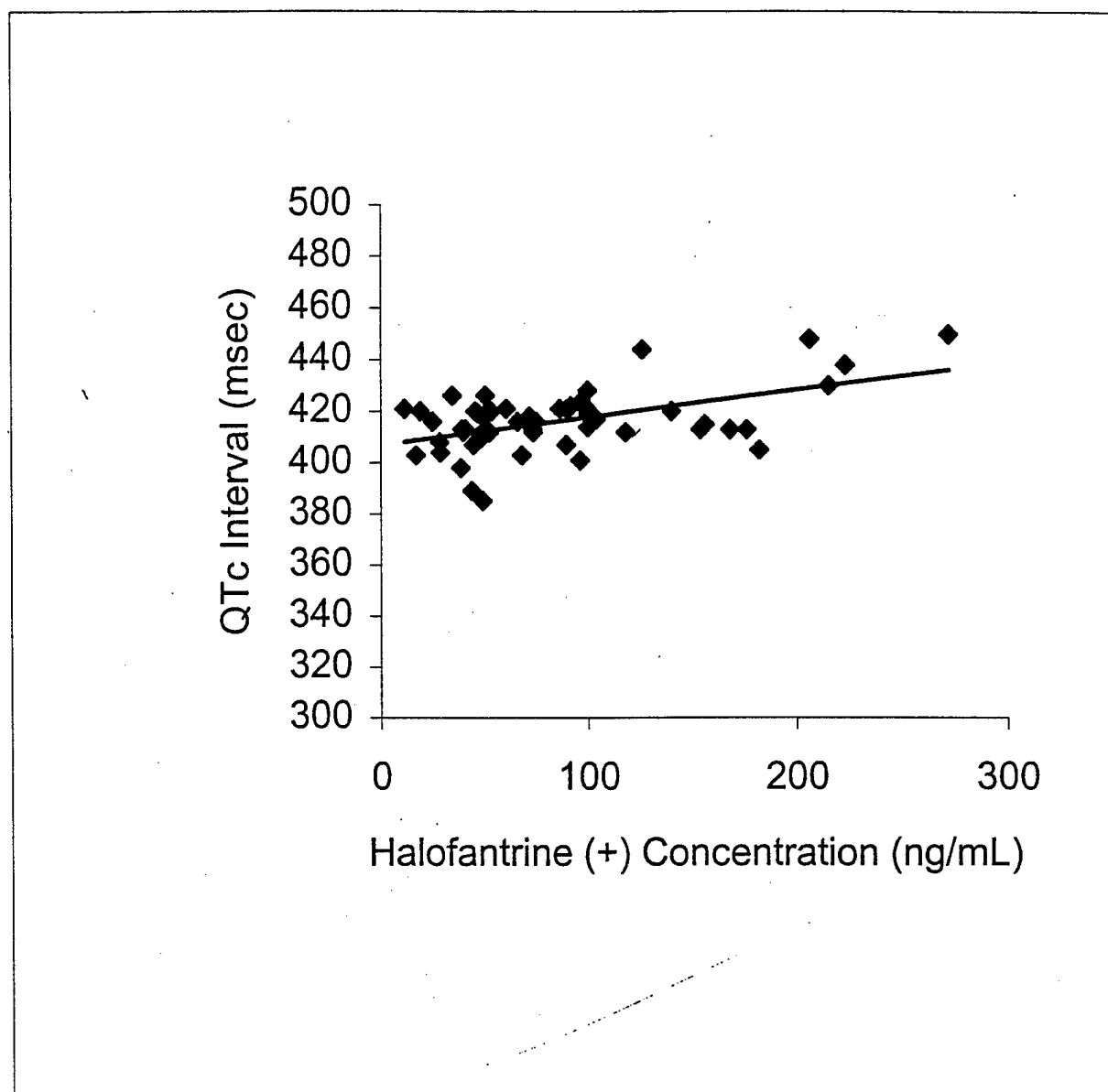
Figure 64b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 11



$$QTc = 433.0 + 0.1025 * Halo(-)$$

Correlation Coefficient (r) = 0.268

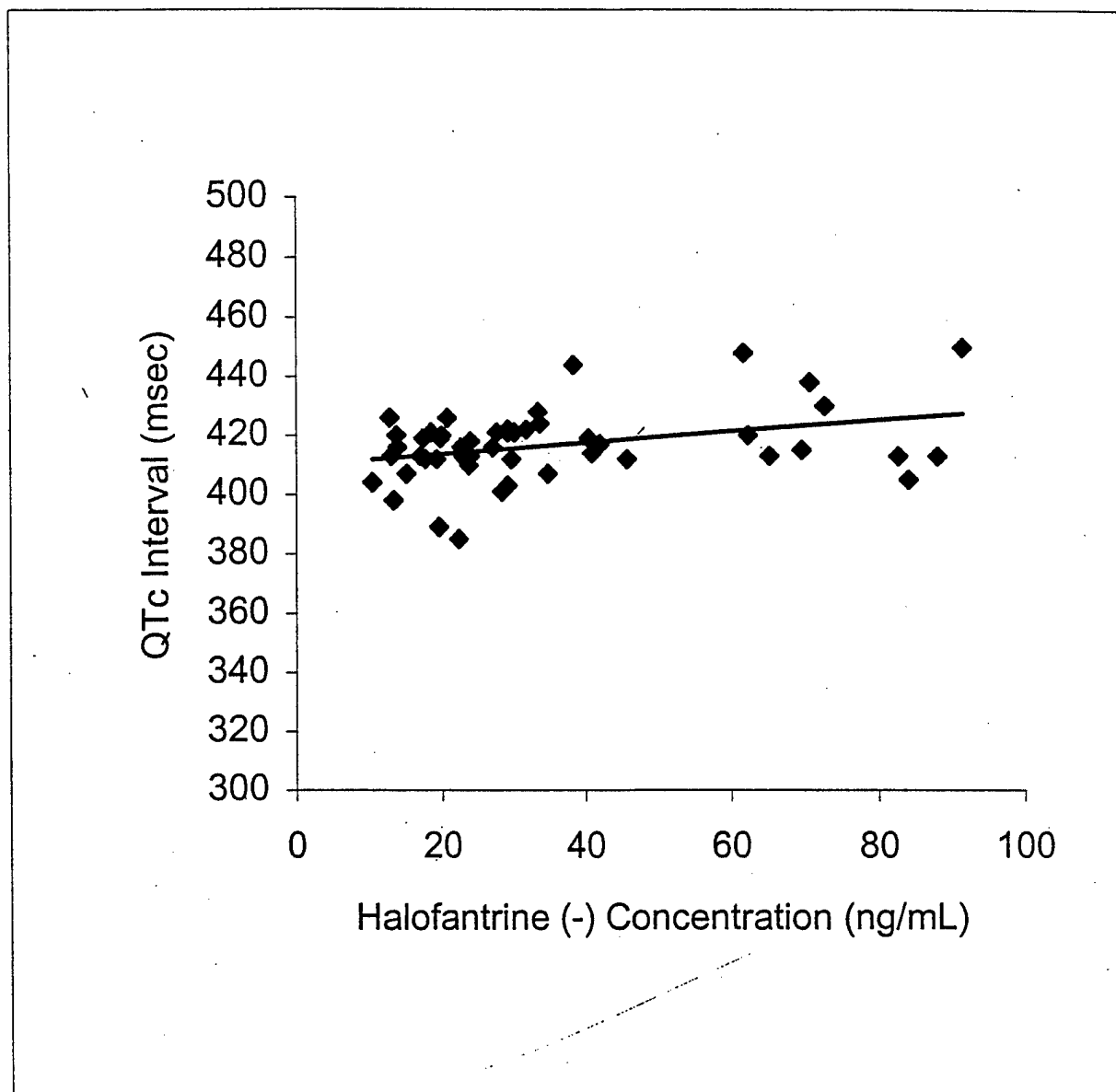
Figure 65a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 14



$$QTc = 407.0 + 0.1075 * Halo(+)$$

Correlation Coefficient (r) = 0.522

Figure 65b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 14

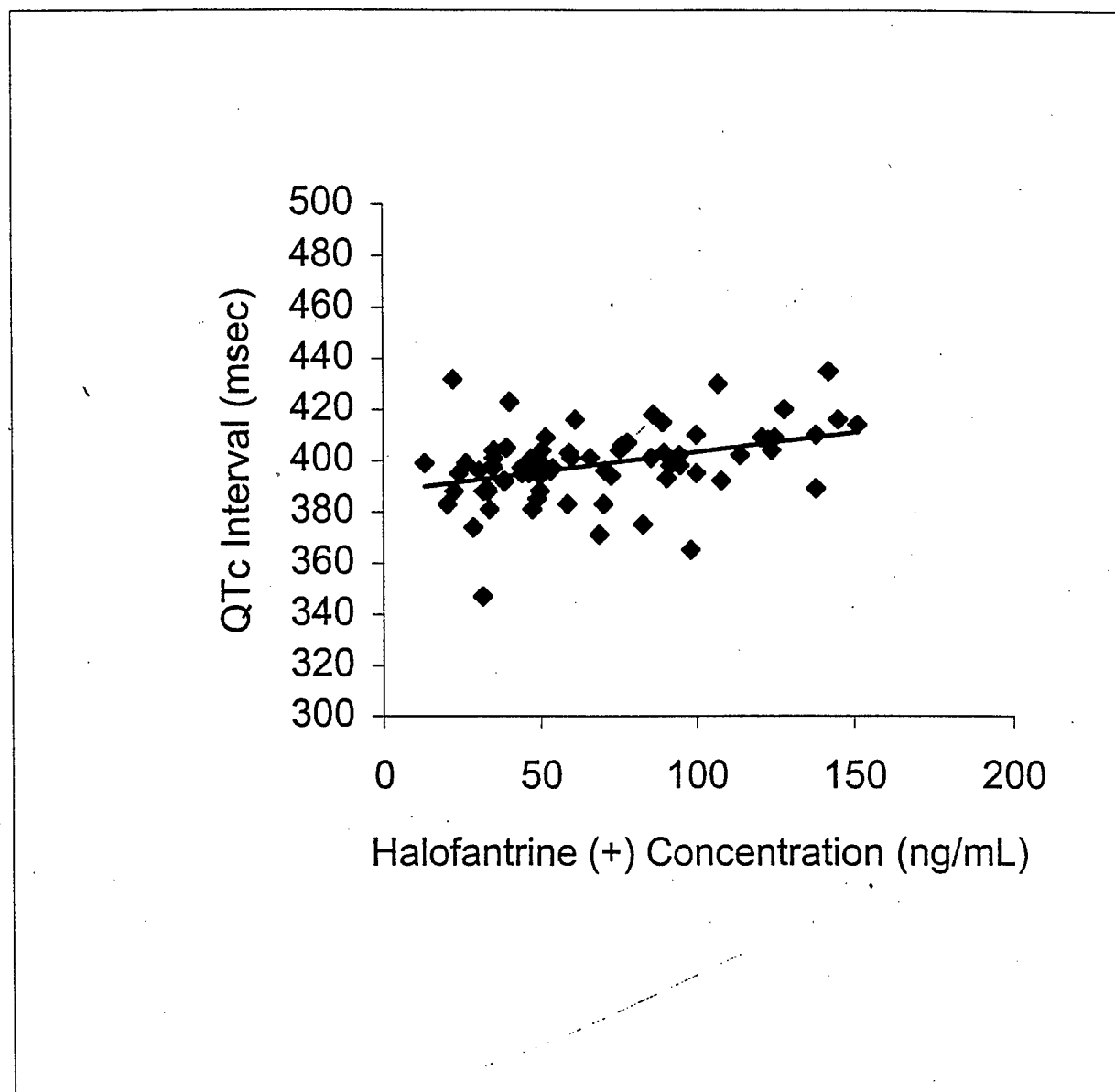


$$QTc = 409.9 + 0.1938 * Halo(-)$$

Correlation Coefficient (r) = 0.352



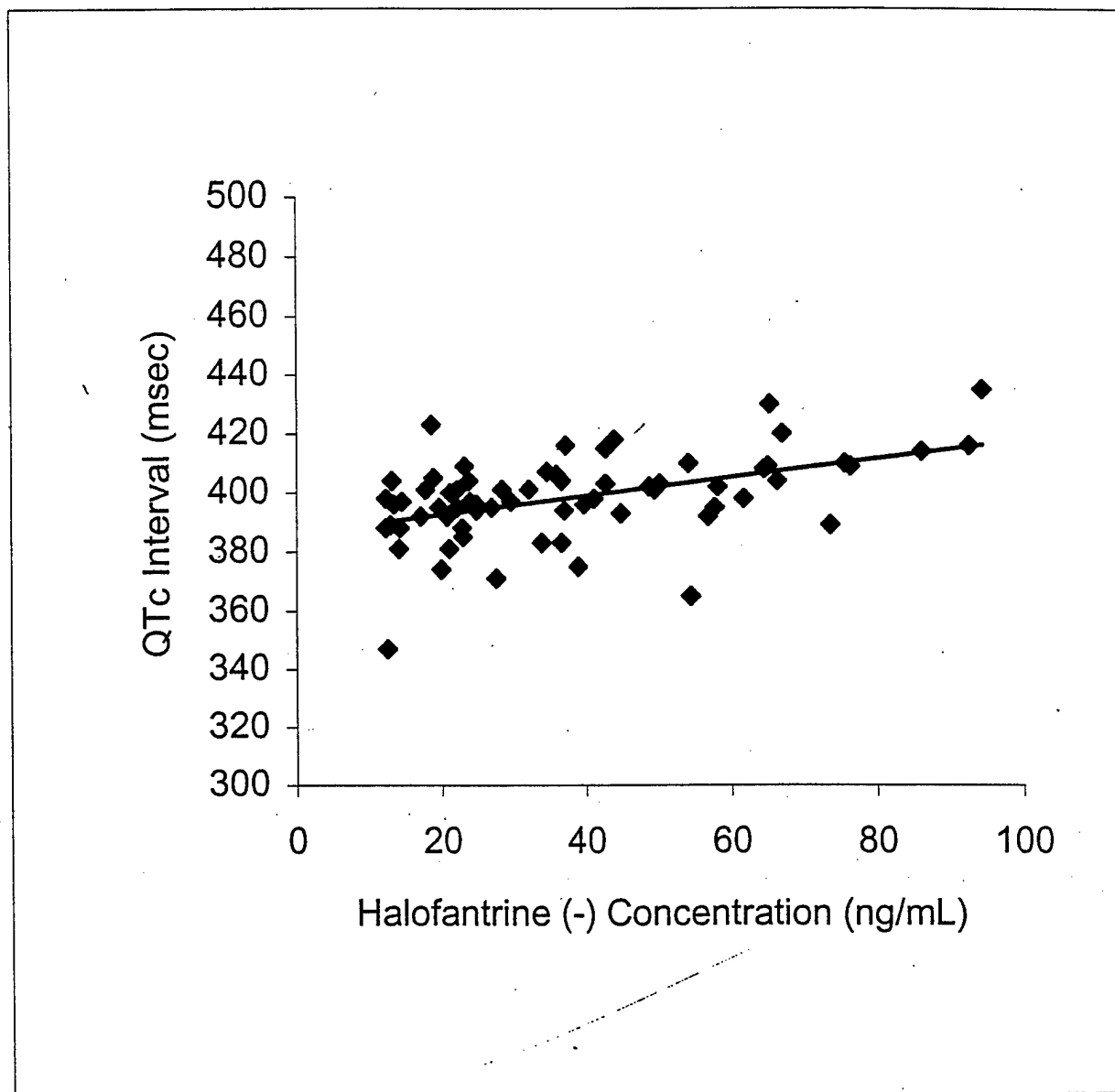
Figure 66a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 15



$$QTc = 387.9 + 0.1539 * Halo(+)$$

$$\text{Correlation Coefficient } (r) = 0.379$$

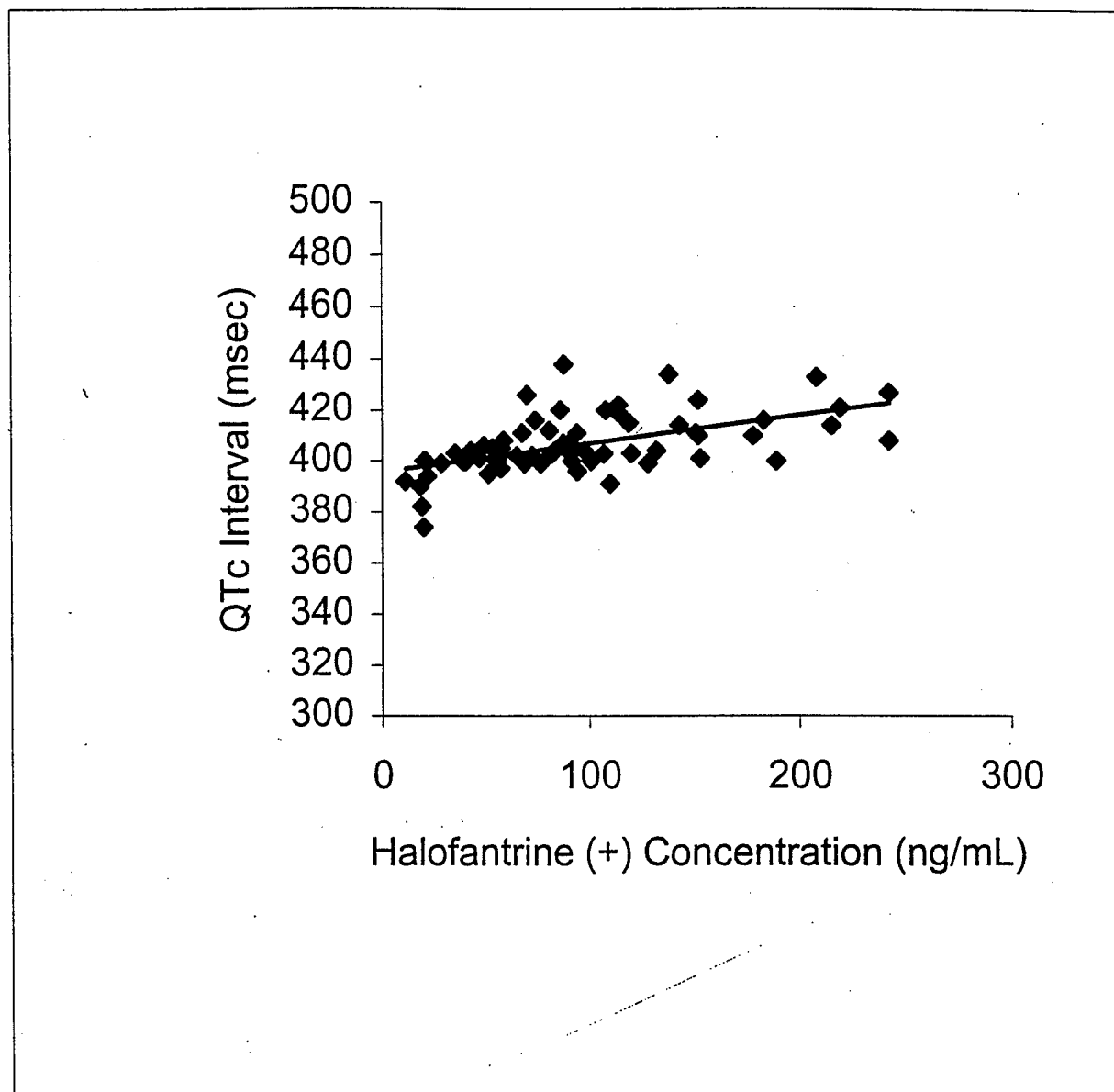
Figure 66b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 15



$$QTc = 386.2 + 0.3180 * Halo(-)$$

Correlation Coefficient (r) = 0.472

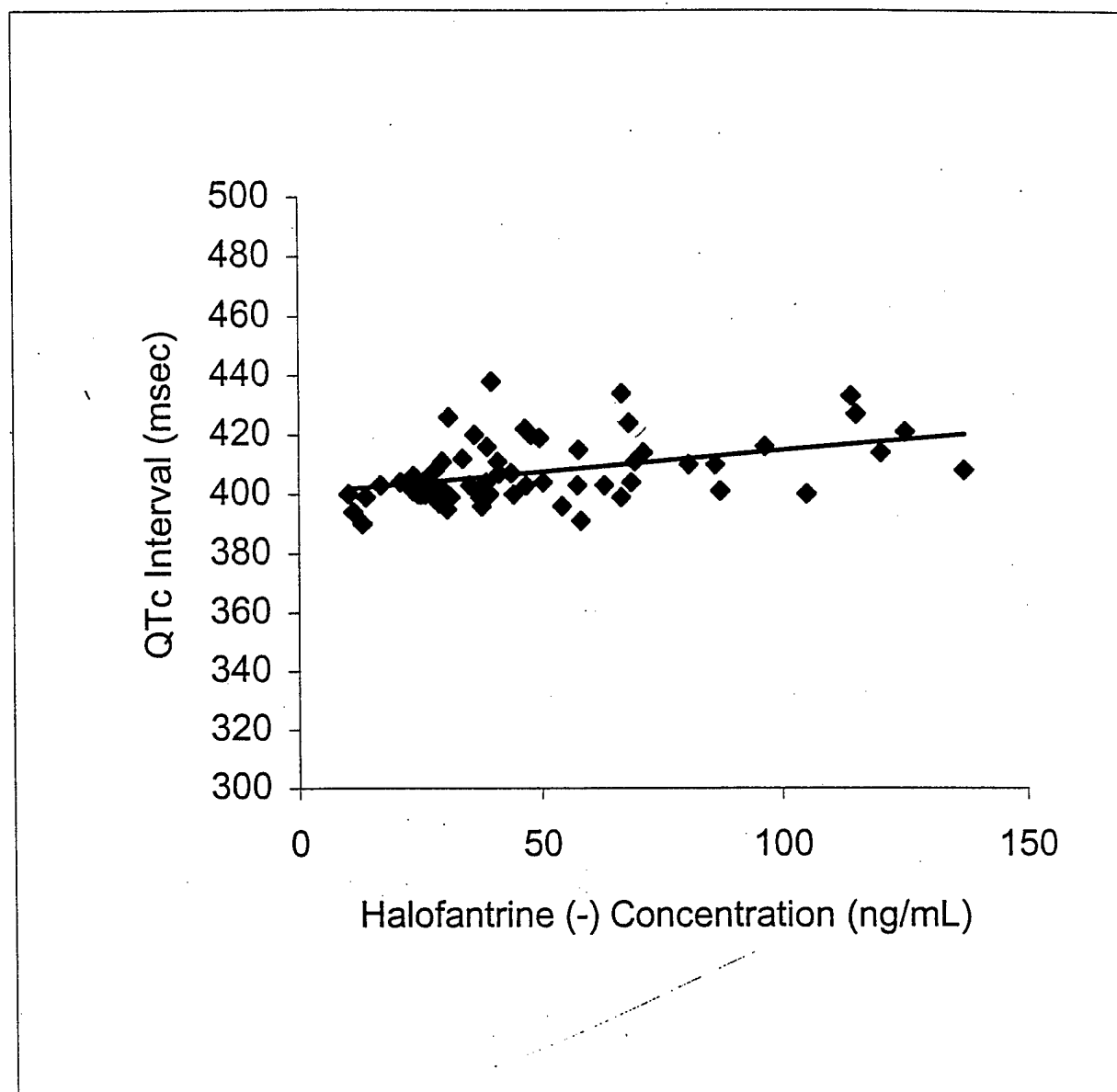
Figure 67a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 16



$$QTc = 395.7 + 0.1125 * Halo(+)$$

Correlation Coefficient (r) = 0.555

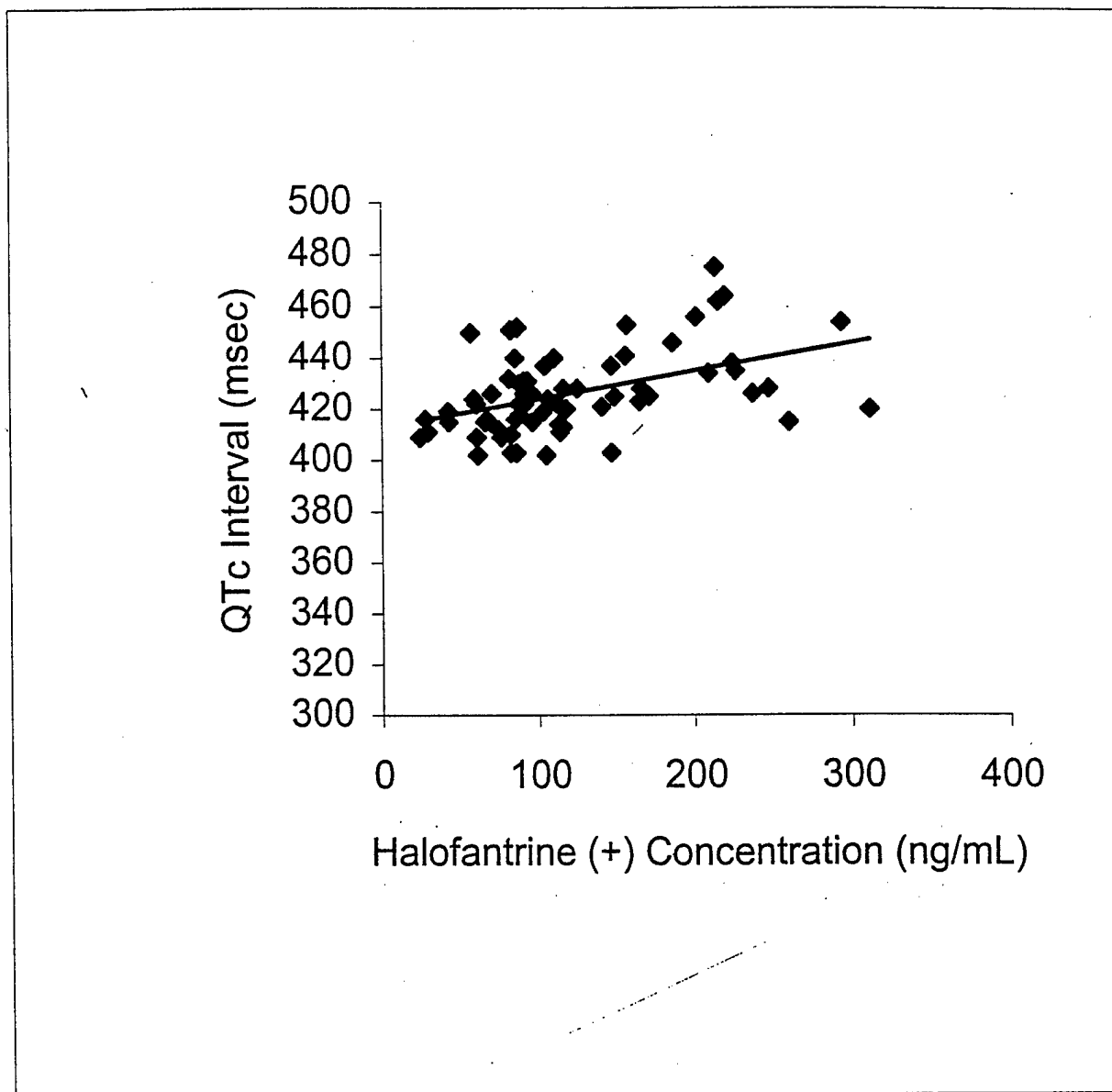
Figure 67b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 16



$$QTc = 400.4 + 0.1452 * Halo(-)$$

Correlation Coefficient (r) = 0.415

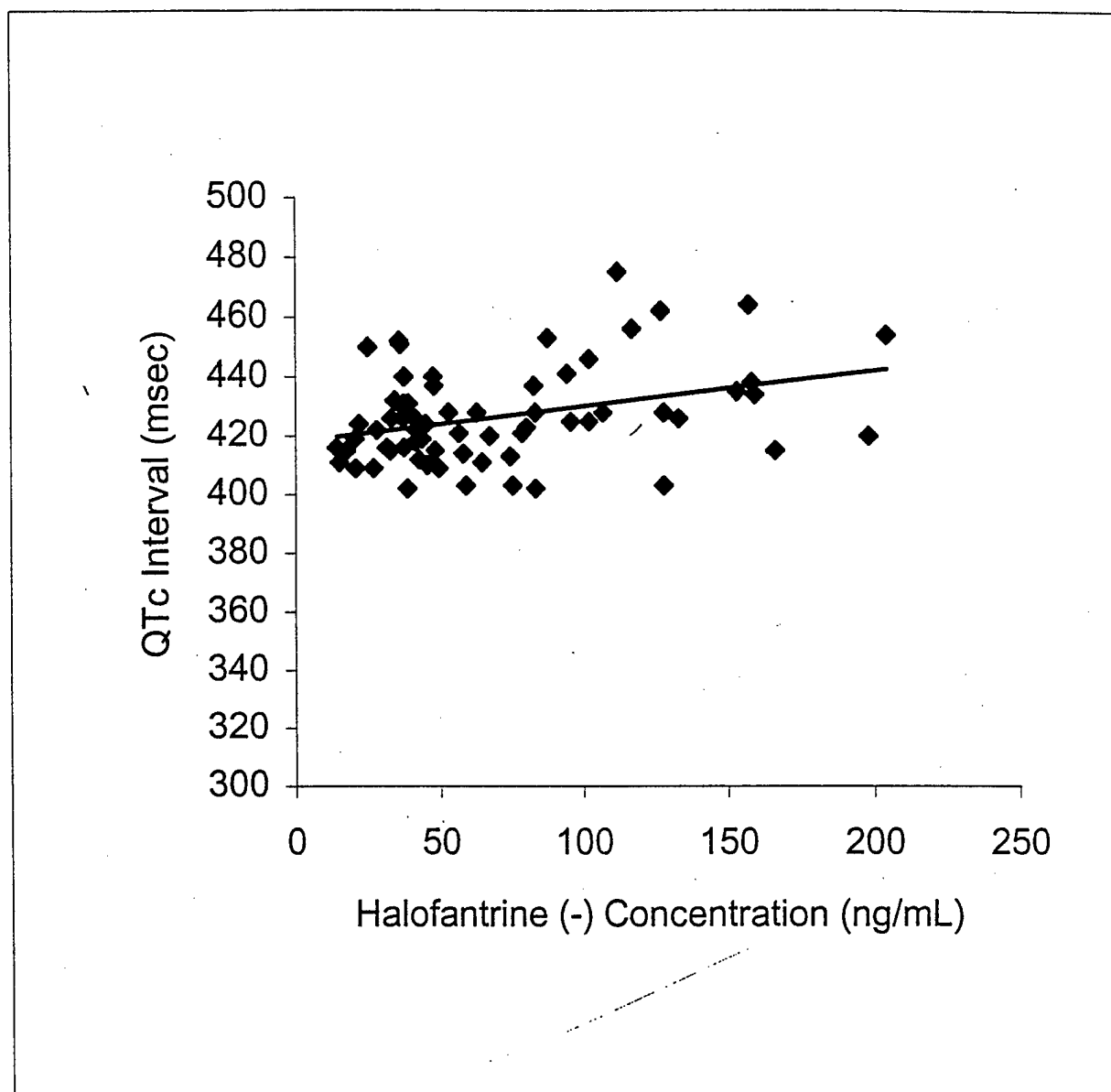
Figure 68a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 18



$$QTc = 412.8 + 0.1112 * Halo(+)$$

$$\text{Correlation Coefficient (r)} = 0.455$$

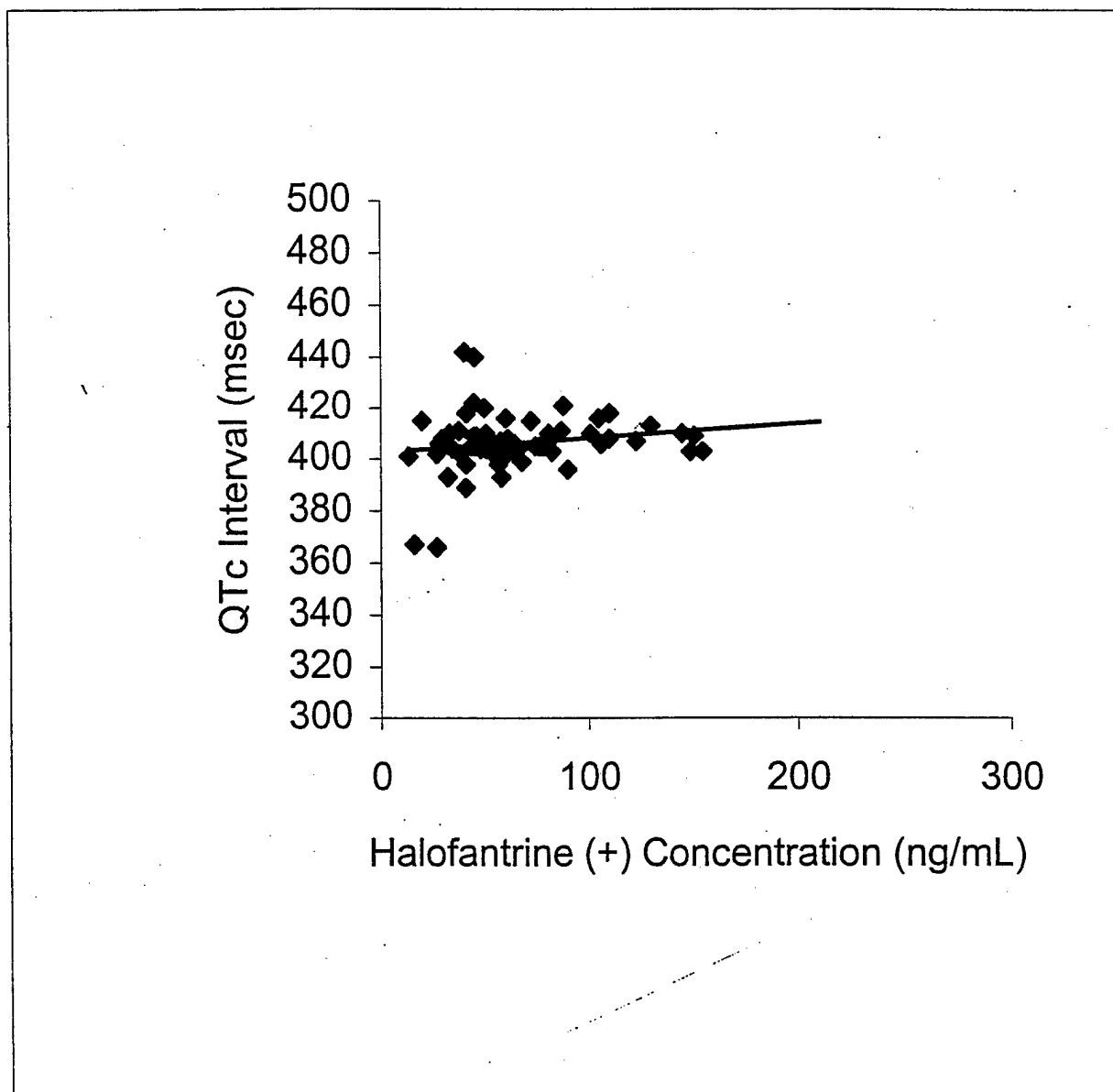
Figure 68b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 18



$$QTc = 418.1 + 0.1203 * Halo(-)$$

Correlation Coefficient (r) = 0.349

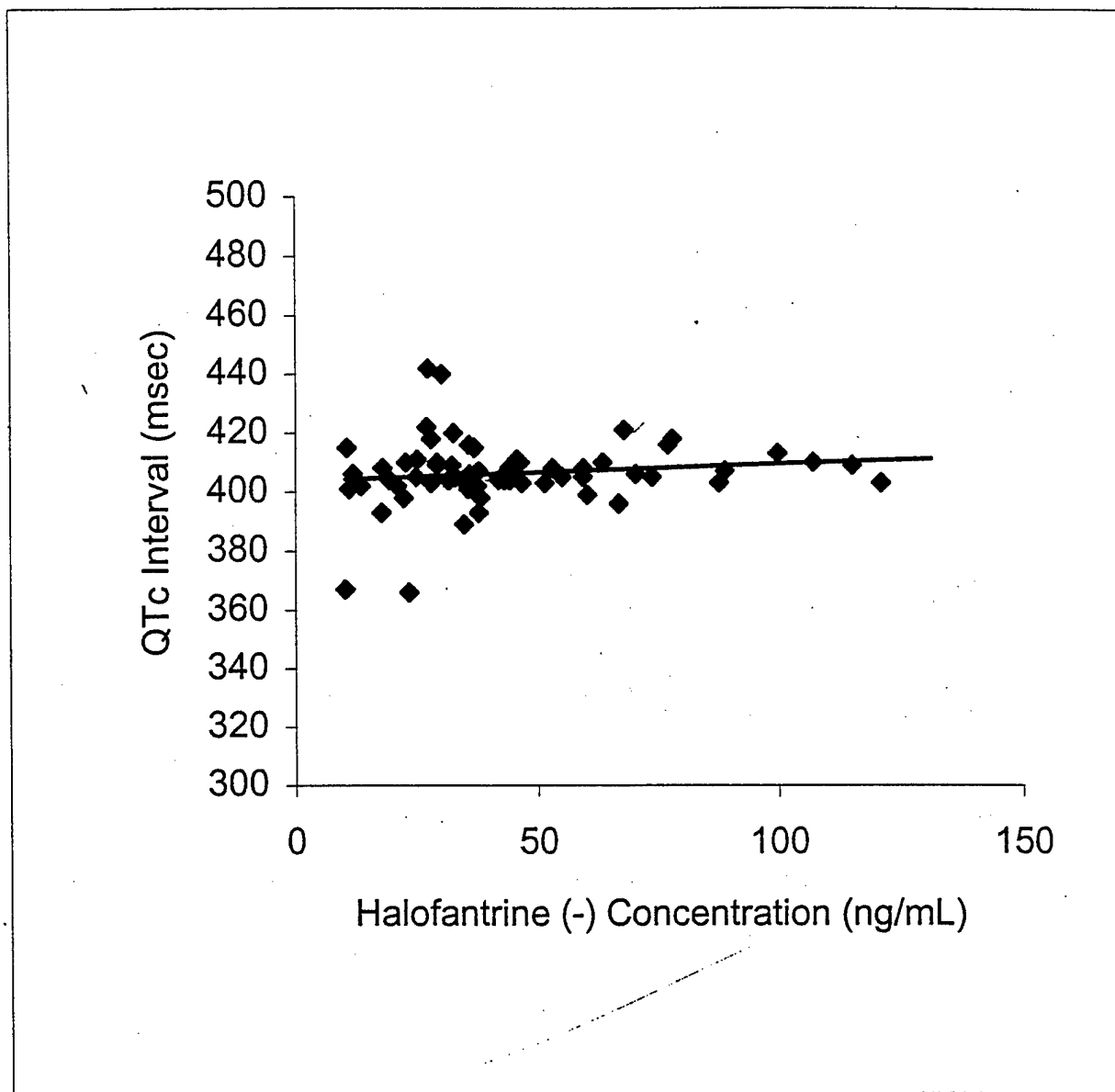
Figure 69a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 19



$$QTc = 402.6 + 0.0566 * Halo(+)$$

Correlation Coefficient (r) = 0.168

Figure 69b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 19

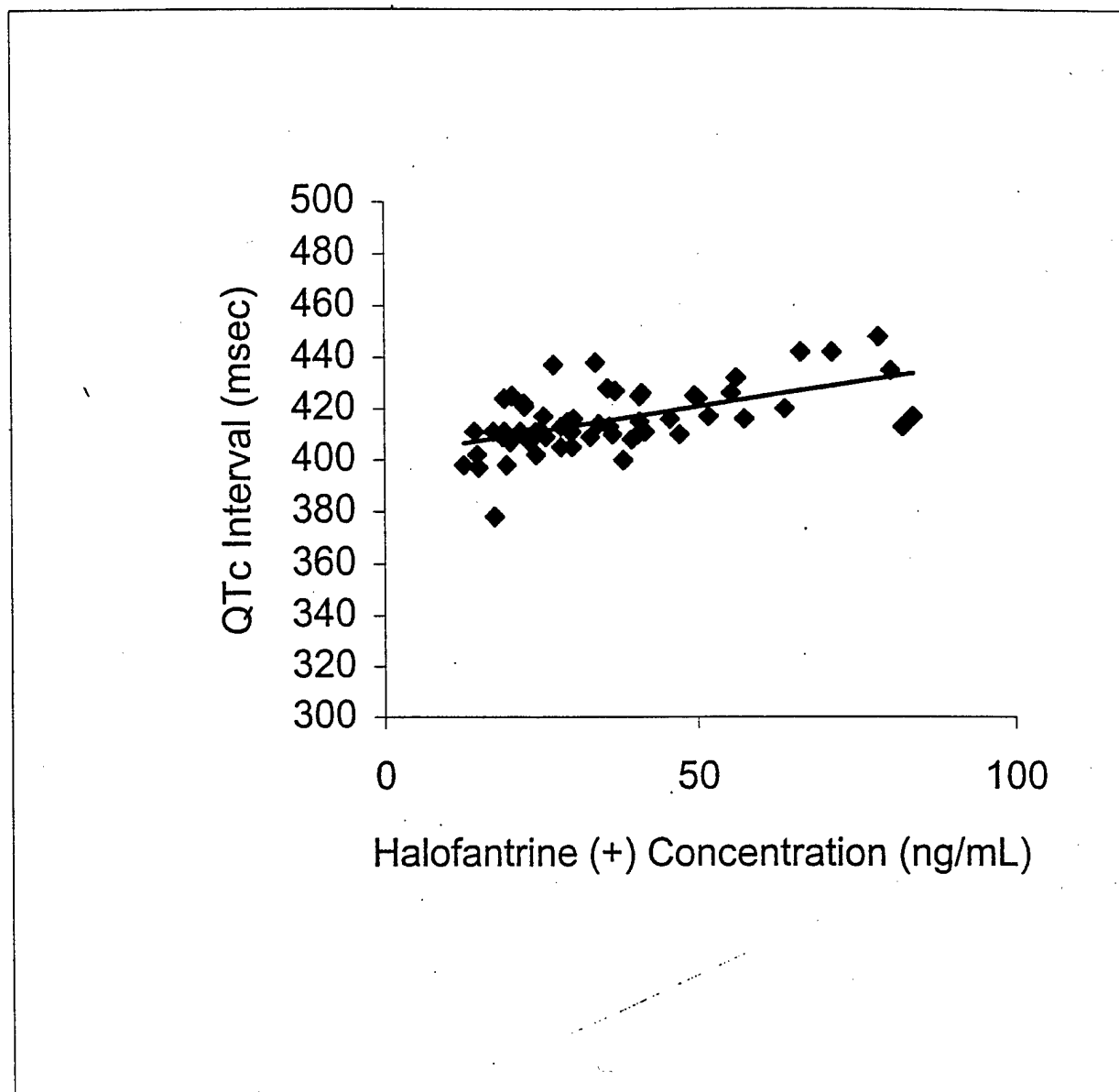


$$QTc = 403.8 + 0.0583 * Halo(-)$$

Correlation Coefficient (r) = 0.131



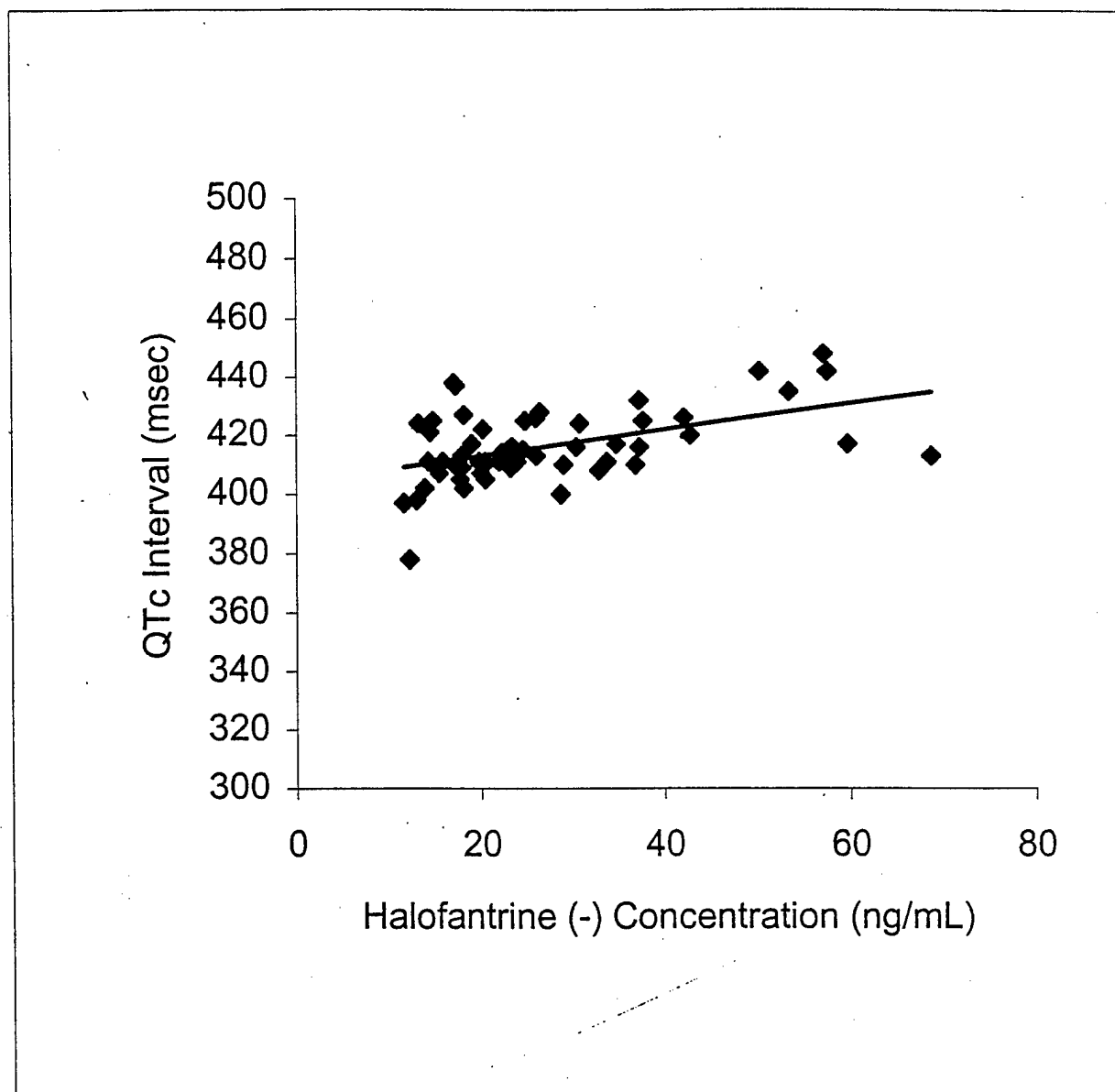
Figure 70a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 20



$$QTc = 401.6 + 0.3849 * Halo(+)$$

$$\text{Correlation Coefficient (r)} = 0.567$$

Figure 70b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 20



$$QTc = 404.0 + 0.4512 * Halo(-)$$

Correlation Coefficient (r) = 0.487